ECHO

USER'S MANUAL

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i. INTRODUCTION

i.1. Identification Data

This document represents the User's Manual of the ECHO, an automatic multi-parameter analyzer for clinical chemistry.

The document has to be intended as a functional part of the ECHO analyzer instrument and the user must read carefully all the sections of this manual, before operate with the instrument.

The manufacturer doesn't take any responsibility related to partial or unauthorized copy of its contents.

i.1.1. Document

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i.1.2. Instrument

- Instrument Part Number EI0002A

i.1.3. Manufacturer

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i.2. Copyright

This document is property of Edif Instruments S.r.l.

Unauthorized copies or alterations of its content could cause legal actions in order to preserve manufacturer's interests.

i.3. International and European Norms Compliance

This document was written according to UNI EN 591: 1996 standard.

The ECHO equipment meets the following directives:

EN 55001

EN 61326-1

i.4. Patents

Currently there are not patents for this instrument.

i.5. Document Intended Purpose

This document represents the User's Manual of the ECHO automatic multi-parameter analyzer.

It is forwarded to laboratory technical personnel that have experience in laboratory practice and in laboratory automated equipments handling.

NOTE: The Manufacturer declares that the information inside this manual have to be considered sufficient to perform a proper use of the referred equipment only in case of readers who have previously followed a manufacturer's specific training course.

i.6. How to Use this Manual

The Manufacturer recommends to read this User's Manual in any of its parts; in particular it is necessary to take care of *notes*, used to specify or to probe concepts previously treated, and of *warnings*, used to emphasize potentially risks or hazards.

All the notes and warnings, written in bold print, must be read carefully, paying particular attention to the following sections:

- Safety (Chapter 1)
- Installation (Chapter 3)
- Maintenance (Chapter 8)

During Laboratory daily operation, it is also suggested by the Manufacturer not to keep this User's Manual too far from the ECHO instrument.

i.7. Index of Contents

Section i - INTRODUCTION

i.1 Identification Data ..... pag. 1
i.1.1 Document ..... pag. 1
i.1.2 Instrument ..... pag. 1
i.1.3 Manufacturer ..... pag. 1
i.2 Copyright ..... pag. 2
i.3 International and European Norms Compliance ..... pag. 3
i.4 Patents ..... pag. 4
i.5 Document Intended Purpose ..... pag. 5
i.6 How to Use this Manual ..... pag. 6
i.7 Index of Contents ..... pag. 7

Section 1 - SAFETY

1.1 General Warnings ..... pag. 1
1.2 Safety Labels ..... pag. 3
1.3 Safety Warnings ..... pag. 4
1.3.1 Installation ..... pag. 4
1.3.2 Operations ..... pag. 4
1.3.3 Maintenance ..... pag. 5
1.3.4 Transport and Storage ..... pag. 5
1.4 Risks Related to the Use ..... pag. 6
1.4.1 Human Hazard ..... pag. 6
1.4.2 Personal Safety Aspects ..... pag. 7
1.4.3 Information on Infectious Liquids and Parts ..... pag. 7
1.4.3.1 Handling ..... pag. 7
1.4.3.2 Dismantling ..... pag. 8
1.4.3.3 Contamination ..... pag. 8
1.5 Recommendations for Optimal Performance ..... pag. 9

Section 2 - SYMBOLS

2.1 List of Used Symbols and Physical Position Overview ..... pag. 1

Section 3 – INSTALLATION

3.1 Equipment Overview ..... pag. 1
3.1.1 Supplied Materials ..... pag. 2
3.1.1.1 Standard Supply List ..... pag. 2
3.1.1.2 List of Options ..... pag. 2
3.2 Installation Constrains ..... pag. 3
3.2.1 Mechanical ..... pag. 3
3.2.2 Environmental ..... pag. 3
3.2.3 Software ..... pag. 3
3.3 Storage ..... pag. 4
3.4 Unpacking ..... pag. 5
3.4.1 Package Characteristics ..... pag. 5
3.4.2 Transport Damages Check ..... pag. 5
3.4.3 Removal From Package ..... pag. 6
3.5 Hardware Installation ..... pag. 7
3.5.1 Electrical Connections ..... pag. 7
3.5.2 Instrument Installation Procedure ..... pag. 7
3.5.3 Fuses ..... pag. 8
3.5.4 Accessories ..... pag. 8
3.5.4.1 Tanks ..... pag. 8
3.6 Software Installation ..... pag. 10
3.6.1 Requirements and Recommendations ..... pag. 10

Section 4 – THEORY OF OPERATION

4.1 Abstract ..... pag. 1
4.2 Principle of Working ..... pag. 3
4.3 Bibliography ..... pag. 5

Section 5 – FUNCTIONS

5.1 Intended Use ..... pag. 1
5.2 Instrument Functions Overview ..... pag. 2
5.3 Functional Subassemblies ..... pag. 4
5.3.1 Working Area ..... pag. 4
5.3.1.1 Reagent Plate ..... pag. 5
5.3.1.2 Sample Plate ..... pag. 6
5.3.1.3 Incubation Plate ..... pag. 6
5.3.2 Pipetting Subassembly ..... pag. 7
5.3.2.1 Sampling Needle ..... pag. 7
5.3.2.2 Aspiration Needle ..... pag. 7
5.3.2.3 Syringe ..... pag. 7
5.3.2.4 Peristaltic Pump ..... pag. 7
5.3.3 Flow Cells ..... pag. 8
5.3.4 Spectrophotometric Reading ..... pag. 8
5.4 Management System ..... pag. 10
5.4.1 Software Architecture ..... pag. 10
5.4.1.1 Main Menu ..... pag. 10
5.4.1.2 Work List ..... pag. 10
5.4.1.3 Execution ..... pag. 10
5.4.1.4 Results ..... pag. 10
5.4.1.5 Chemistries ..... pag. 11
5.4.1.6 Service ..... pag. 11

Section 6 – PERFORMANCE CRITERIA AND LIMITATIONS

6.1 General Statement ..... pag. 1
6.2 Photometer ..... pag. 3
6.2.1 Precision ..... pag. 3
6.2.2 Accuracy ..... pag. 4
6.2.3 Linearity ..... pag. 5
6.3 Pipettor ..... pag. 7
6.3.1 Precision ..... pag. 7

6.3.2 Accuracy ..... pag. 8
6.4 Carry-Over ..... pag. 9

Section 7 – OPERATING PROCEDURES

7.1 Preparation Prior Operations ..... pag. 1
7.1.1 Safety Recommendations and Remarks ..... pag. 1
7.1.1.1 User Skill Level ..... pag. 1
7.1.2 Instrument Setup ..... pag. 2
7.1.2.1 Instrument Built-in On Line Test ..... pag. 2
7.1.3 Sample Handling ..... pag. 3
7.1.3.1 Sample Type ..... pag. 3
7.1.3.2 Pre-treatment ..... pag. 3
7.1.3.3 Preservation ..... pag. 4
7.1.3.4 Sample Minimum Volume ..... pag. 4
7.1.3.5 Dead Volume ..... pag. 4
7.1.4 Reagent and Disposable Materials ..... pag. 4
7.1.4.1 Use ..... pag. 5
7.1.4.2 Preservation ..... pag. 5
7.1.5 Fixture and Accessories ..... pag. 5
7.2 Management System Overview ..... pag. 6
7.2.1 How To Start ..... pag. 6
7.2.2 Main Menu ..... pag. 7
7.3 Chemistries Menu ..... pag. 9
7.3.1 Edit Methods ..... pag. 10
7.3.1.1 Types Selection ..... pag. 12
7.3.1.2 Filters Selection ..... pag. 13
7.3.1.3 Incubation Time ..... pag. 13
7.3.1.4 Stabilization Time ..... pag. 14
7.3.1.5 Reading Time ..... pag. 14
7.3.1.6 Reagent 2 – Incubation Time ..... pag. 14
7.3.1.7 Reagent Position ..... pag. 14
7.3.1.8 R1 Reagent Volume ..... pag. 14

7.3.1.9 R2 Reagent Volume ..... pag. 15
7.3.1.10 R3 Reagent Volume ..... pag. 15
7.3.1.11 Sample Volume ..... pag. 15
7.3.1.12 Numbers of Calibration Standards ..... pag. 15
7.3.1.13 Numbers of Controls ..... pag. 16
7.3.1.14 Standard Position ..... pag. 16
7.3.1.15 Control Position ..... pag. 16
7.3.1.16 Standard Value ..... pag. 16
7.3.1.17 Factor ..... pag. 17
7.3.1.18 Number of Curves ..... pag. 18
7.3.1.19 Description of the Curve ..... pag. 19
7.3.1.20 Substrat Depletion ..... pag. 19
7.3.1.20 bis Sample dilution ..... pag. 19
7.3.1.21 Dilution Ratio ..... pag. 19
7.3.1.22 Linearity ..... pag. 20
7.3.1.23 Reagent blank value: min ..... pag. 20
7.3.1.24 Reagent blank value: max ..... pag. 20
7.3.1.25 Normal Value: min ..... pag. 20
7.3.1.26 Normal Value: max ..... pag. 21
7.3.1.27 Measure Unit Selection ..... pag. 21
7.3.1.28 Washings Number ..... pag. 22
7.3.1.29 Blank Reagent Selection ..... pag. 23
7.4 Patient Handling ..... pag. 25
7.4.1 Edit Work List ..... pag. 26
7.4.2 Load Work List ..... pag. 31
7.4.3 Display Work List ..... pag. 32
7.4.4 Print Work List ..... pag. 33
7.4.5 Print Profile List ..... pag. 33
7.5 Operative Procedure ..... pag. 34
7.5.1 Batch ..... pag. 36
7.5.1.1 Tests and Control Selection ..... pag. 37
7.5.1.2 Standardisation Procedure ..... pag. 38

7.5.1.3 Execution ..... pag. 41
7.5.1.4 Automatic sample dilution ..... pag. 43
7.5.1.5 Automatic standard dilution ..... pag. 43
7.6 Result Handling ..... pag. 44
7.6.1 Display Results ..... pag. 45
7.6.2 Print Results ..... pag. 46
7.6.3 Repetitions ..... pag. 47
7.6.3.1 Repetition of One Test ..... pag. 48
7.6.3.2 Repetition of One Patient ..... pag. 49
7.6.4 Controls ..... pag. 50
7.7 Urgent Analysis ..... pag. 52
7.8 Dismantling ..... pag. 52
7.8.1 Reagents, Consumable and Toxic ..... pag. 53
7.8.2 Instrument and Components ..... pag. 53

Section 8 - MAINTENANCE

8.1 User Maintenance Basics ..... pag. 1
8.1.1 Competence ..... pag. 1
8.1.2 Cleaning ..... pag. 2
8.1.3 Disinfection ..... pag. 2
8.1.3.1 Instrument Disinfection Procedure ..... pag. 2
8.1.3.2 Metallic Needle ..... pag. 3
8.1.3.3 Waste Tube (External) ..... pag. 3
8.1.3.4 Waste Tank ..... pag. 3
8.2 User Maintenance Warnings ..... pag. 4
8.3 User Daily Maintenance Procedure ..... pag. 5
8.4 User Weekly Maintenance Procedure ..... pag. 6

Section 9 – TROUBLESHOOTING

9.1 Normal Operation Basics ..... pag. 1
9.2 Diagnostic System ..... pag. 1
9.3 Trouble Sources Classification Remarks ..... pag. 1

9.4 Correct Operations Messages ..... pag. 1
9.5 Error Messages List and User Required Actions ..... pag. 2
9.6 Competence ..... pag. 8

Section 10 – TECHNICAL SPECIFICATIONS

10.1 Instrument Technical Specification ..... pag. 1
10.1.1 Sample Loading ..... pag. 1
10.1.2 Sera and Reagent Pipetting Station ..... pag. 2
10.1.3 Incubating Station ..... pag. 2
10.1.4 Photometric Reading ..... pag. 2
10.2 Adjustments and Settings ..... pag. 3
10.3 Electrical Requirements ..... pag. 4
10.4 Operating Environmental Requirements ..... pag. 5
10.5 Storage Environmental Requirements ..... pag. 6
10.6 Emissions ..... pag. 7
10.7 Electromagnetic Compatibility ..... pag. 8
10.8 Consumptions ..... pag. 9

Section 11 – SUPPLEMENTARY INFORMATION

11.1 Short Users Instruction ..... pag. 1
11.2 Warranty Limitations ..... pag. 2
11.3 Spare Parts and Consumables ..... pag. 3
11.4 Ordering Information ..... pag. 4
11.5 Technical Assistance ..... pag. 5
11.6 Forms ..... pag. 6

Section 12 – GLOSSARY

12.1 List of Acronyms and Abbreviations ..... pag. 1
12.2 List of Terms ..... pag. 2

1. SAFETY

The safety precautions and regulations included in this section must be strictly observed by the User.

The use of the Instrument for purposes other than those specified in Chapter 5 will automatically invalidate any warranty agreement.

The user must not carry out any kind of alteration on the Instrument, included software manipulations. Every unauthorized change or modification and not observance of the maintenance procedures will immediately invalidate warranty agreements.

1.1. General Warnings

All notes and warnings in this Manual which are in bold and/or underlined must be read carefully, paying particular attention to the following sections:

- Installation (Section 3)
- Disinfections Procedures (Section 8)

All assay methods must be validated on the analyzer before carrying out any laboratory routine. Such validation must include:

- Make sure that the instrument correctly handling the various reagents, with reference to:
  - Aspiration, transfer and distribution of the liquid
  - Liquid mixing (if required) without bubble or froth formation, which may create problems in later stages of the process.
- Reliability of materials used for the procedure (sample tubes, reagent and/or control vials, microplates, etc).
- Accurate calculation: ensure that the software calculations give results comparable to those obtained using the methods specified by the assay manufacturer.

These procedures are normally validated by the distributor: if the required data are not available for any particular assay, the user must validate these procedures himself.

Any modification made to pre-validated procedures must be validated again.

The User should always check the proper closure of the Instrument covers, during the use of the instrument.

The User must always assure himself that all Instrument technical activities related to installation, performance verification and repair are carried out by qualified personnel.

All precautions and recommended practices normally used in the laboratory (Good Laboratory Practice) must be followed: this is particularly important because the diagnostic tests are carried out automatically by the analyzer.

1.2. Safety Labels

Infective tank warning

This label is placed on the external tank for the waste and near the peristaltic pumps. It informs the user about the contamination risk for the part where it is placed.

ATTENZIONE

SERBATOIO POTENZIALMENTE INFETTO

WARNING

POTENTIALLY INFECTIVE TANK

Electrical risk warning

This label is placed on the back of the instrument and it informs the user about electrical risk.

WARNING

HIGH VOLTAGE INSIDE DO NOT OPEN CABINET, REFER TO QUALIFIED PERSONNEL

1.3. Safety Warnings

To reduce the risk of electric shock, keep away from live circuits. The instrument must be connected to a ground point. The instrument is equipped with a three-core cable to be connected to a 220 Vac or 110 Vac power socket.

1.3.1. Installation

On customer demand, the installation, verification and calibration of the instrument, will be carried out by qualified technical personnel. They should take reasonable steps to ensure that the location in which the equipment is to be installed meets the environmental and electromagnetic specifications for the analyzer. Any significant movement of the equipment should be carried out by qualified personnel.

If the instrument has the refrigerated plate option, a free air space of at least 10 cm is necessary to allow air-cooling inlet, placed on the bottom of the instrument, on the left side.

1.3.2. Operations

If the ECHO is used for automated clinical chemistry analysis; the Manufacturer reminds the Users that failures following safety precautions and regulations could produce false negative results reporting.

For these reasons, particular care must be carried out by the operator to the following points:

- Use only test procedures or assays pre-validated by the Manufacturer or its distributor;
- Don’t introduce any modification on pre-validated procedures or assays;
- Avoid to use vials other then Manufacturer suggested types;

Particular care must be observed for the instructions provided by the Manufacturer in order to perform correct switching on and off procedures.

NOTE: The Manufacturer reminds to the User that safety precautions failure could produce human hazard, risk or damages both for operator and patient.

1.3.3. Maintenance

The User must carry out the maintenance procedures quoted in Chapter 8, in order to assure a correct operation of the instrument and the reliability of the assay results.

NOTE: The Manufacturer remarks to the User that continuous Instrument visual inspection is the first and easier way to guarantee the best equipment performances.

User's maintenance tasks must observe the following safety recommendations:

- Read carefully the instruction on Chapter 8 before starting with maintenance;
- Clean every part of the Instrument only using soft cloths;
- Remove immediately spills or sketches from the working planes, if any;
- Use only non corrosive solutions;

WARNING

All User maintenance tasks must be carried out with the Instrument in OFF state and with the main power cable disconnected from the power socket.

1.3.4. Transport and Storage

Take care during the transport and the unpacking of the instrument.

To store the instrument read carefully Section 10.6 'Storage Environmental Requirements'.

1.4. Risks Related to the Use

The Manufacturer reminds that the use of the Instrument doesn't assure the absence of exposure to BIOHAZARD so the Instrument must be always handled as potentially infected device.

The Manufacturer declares that information provided through this manual have to be consider sufficient to perform a "free of risk" usage of the referred equipment only in case of readers that previously exceed a manufacturer's specific training course.

To reach the full throughput condition of the Instrument and to assure at the same time the user safety, the Manufacturer recommends, considering both the operator and the patient point of view that the daily operators have to be also previously trained to the operating system basic usage.

The Manufacturer also assumes that all precautions and recommended practices normally used in the laboratory (Good Laboratory Practice) must be applied by the Instrument operators.

NOTE: To avoid running additional risks, do not make any unauthorised modifications; any kind of alteration should be made with the prior authorisation of the manufacturer.

1.4.1. Human Hazards

Particular safety items against human hazards are the following:

- Do not eat, drink or smoke in the laboratory;
- Wear the lab coats at all time and particularly near the Instrument placement point.

1.4.2. Personal Safety Aspect

The Manufacturer declares that the Instrument and all its internal parts were designed and manufactured to prevent any possible risk for the operator safety.

It is mandatory, for the operator safety, to install an emergency breaker at not more than one meter from the Instrument.

1.4.3. Information on Infectious Liquids and Parts

The use of the instrument doesn't assure the absence of exposure to biohazard.

The Manufacturer remarks to the User that all parts of the Instrument that could come into direct contact with blood or sera, including positive controls, and/or reagent must always be treated as potentially infected materials.

WARNING

The instrument must be always handled as potentially infected device.

1.4.3.1. Handling

When handles potentially contaminated sera, the operator must wear:

- Lab coat
- Disposable gloves
- Safety glasses

in order to avoid splashes and/or spilling of the infectious liquids that could come into contact with any exposed part of the body.

Take special care when you handle the following parts of the instrument:

- Metal needles
- Waste tank

because they could be contaminated: they come in contact with sera and reagents.

Eventual tools and instruments used during technical intervention must be sterilised, before putting them back into their cases.

1.4.3.2. Dismantling

All waste materials, including both liquids and solid, must be dismantled according with regional laws and local regulations.

WARNING

The Manufacturer remarks to the user that all waste materials must always be treated as potentially infected materials.

In case of replacement of faulty parts, each broken parts, dismounted from the Instrument just by manufacturer or local distributor qualified personnel, must be handled as potentially infected materials.

The Manufacturer declares that all technical personnel have exceed a specific training course related to infected materials treatment.

WARNING

All parts dismounted from the Instrument that could have been entered in direct contact with possible contamination sources must be subjected to a valid decontamination process before leaving the User's medical laboratory.

The dismantling of the product should be carried out by applying the national regulations, referring to the local environment authority, taking into consideration that the instrument is manufactured with no noxious materials for the environment.

1.4.3.3. Contamination

Risks of contamination exist only during the operations of loading/unloading; with regard to this, see section 1.4.3. (Information on Infectious Liquids and Parts). During the instrument operation there are not contamination risks because the instrument, in this step, doesn't need the user intervention.

1.5. Recommendations for Optimal Performance

The User must observe the following recommendations in order to get the specified performance from the instrument.

- Fill sample vials out of the instrument, in order to avoid spilling of liquids on the ECHO working area.

- The user must ensure that, when placing test tubes or vials into the analyzer, these are properly seated.

- If the laboratory does not have back up power supplies, a standby system (UPS) providing at least 1.5 kW, should be used to provide power during short-term cuts.

WARNING

Use of the instrument for purposes other than specified, indicated or agreed upon with the manufacturer, will automatically invalidate all warranties. The manufacturer reserves the right to take any legal action to protect all its interests.

2. SYMBOLS

No symbols are applied on this version of ECHO.

3. INSTALLATION

3.1. Equipment Overview

The ECHO is provided with internal LCD screen, that allows to control all its functions and operation. Its working area is planned to work in safety and with maximum productivity; it enclose the reagent plate, where are placed the reagent tubes, the sample plate, that contains the sample vials, ant the incubation plate.

3.1.1. Supplied Materials

In the following sections are listed the supplied materials, subdivided in a standard supply list and in a list of options.

3.1.1.1. Standard Supply List

	EDIF CODE	OLD CODE	
1	EI0703CV1	P10 0000 0023	Halogen lamp (MATE-N-LOCK connector)
1	EI0801B	P10 0000 0008	Tubes kit
1	EI0802A	P10 0000 0010	Sampling and Aspiration Needles kit
1	EI0710A	P10 1000 0001	Reagent bottles 25 ml (27 pos.) pack (30 pcs)
1	EI0711A	P10 1000 0002	Reagent bottle caps 25 ml (27pos.) pack (30 pcs)
1	EI0714A	P10 0000 0003	Needle cleaning filters pack
1	EI0715A	P10 0000 0004	Reaction segments pack (100 pcs)
1	EI0716A	P10 0000 0005	Serum cups pack (1000 pcs)
1	EI0717A	P10 0000 0006	Thermal paper pack (3 pcs)
1	EI0702B	P10 0000 0012	Fuses kit (230V)
1	EI0721A	P10 0000 0017	Water charge bottle
1	EI0722A	P10 0000 0018	Waste bottle
1	EE0203A	S10 2100 0009	Null modem host cable
1	EI0702B	P10 0000 0012	Fuses kit 230V
1	EI1126A		Brief user manual
1	EI0732A		Documentation CD
1	EE0202B		Power cord

3.2. Installation Constrains

During the installation of the ECHO, the operator has to observe mechanical and environmental constrains in order to assure a correct instrument operation.

3.2.1. Mechanical

ECHO should be positioned on a working bench, at least 1 meter long, free of vibrations and far from electromagnetic sources (big electrical motors, elevators, therapeutic equipment, X rays etc.) and with a good ground connection.

The working bench must be a robust table, to prevent the oscillation of the instrument: the table should be as flat as possible and capable of bearing the weight of the instrument.

3.2.2. Environmental

The place where the instrument will be installed should be possibly an air-conditioned room, to have a firm temperature and a correct degree of humidity. Avoid the direct exposure to the sunbeam.

Allow a working space around the instrument of at least 50cm. However, if space facilities are restricted and the instrument has the refrigerated plate option, the air intake located on the bottom of the instrument, on the left side, must have a free air space of at least 10 cm.

3.2.3. Software

The ECHO software is a firmware multitask application purposely realized for this instrument; it has characteristics of reliability and use facility. It is recorded on the two EPROMS mounted on the CPU board.

An internal mini-PC with a DOS Terminal program is used for the video, keyboard, external printer and host interface.

3.3. Storage

To store in the right way the instrumentation, it is recommended to store it in a dry area and to observe the storage environmental requirements listed in section 10.6.

Remember that the instrument must be stored exclusively in its original wood packing and that the operations for the storage must be carried out only by authorized personnel.

3.4. Unpacking

Before proceeding to unpacking the instrument, check that all constrains and environmental conditions are met – refer to section 10 Technical Specifications.

3.4.1. Package Characteristics

ECHO is normally despatched in a box made of cardboard studied to give the best protection to the instrument, during transportation in normal conditions. The original packing can be re-used if the instrument has to be moved or sent back.

3.4.2. Transport Damages Check

Check the package carefully for damages. The eventual damages caused by the transport should be contested immediately to the shipping company and noted on the delivery note.

Once the goods are delivered to the shipping company, the responsibility for its integrity is his until the delivery of the goods.

If you find some anomalies:

1) Do not refuse the shipment
2) On the receipt of delivery, write a note on the fact
3) Do not remove the package! Leave the instrument in the original package, and request immediate inspection from carrier within 15 days from delivery – if the delivery is international, the inspection must be requested within 3 days from delivery.

NOTE: Check if the above procedure is in conformity with local regulations and/or special agreements with the shipper.

3.4.3. Removal from Package

Open the boxes and extract the instrument carefully.

Verify that all the parts described in the delivery note are present, including the welcome kit as well.

Control the serial number of the instrument, if the same corresponds to the one indicated in the delivery note.

Remove the lid and then remove the two lateral elements that secure the instrument.

At least two persons are needed to move the instrument from its box to the working table. Lift the instrument up and place it on the working bench (the one on which the instrument is destined to be operated upon).

Hardware Installation

ECHO is a sophisticated high precision instrument. A correct installation will assure the good functionality of the instrument. We suggest to execute the installation by the technical staff of the I.S.E. S.r.l. or by staff trained by I.S.E. S.r.l. and make sure to carry out a complete start up of the instrument before operation.

For detailed safety instructions read carefully Section 2.

3.5.1. Electrical Connection

In compliance with the safety precautions listed at the beginning of this manual, to reduce the risk of electric shock, the instrument should be connected to a ground point. The instrument is equipped with a three-core cable for connection to a 220 V or 110 V power socket. Therefore connect the power cord, situated on the back of the instrument, to a 115 or 230 VAC 50/60 Hz grounded receptacle.

NOTE: Although ECHO is equipped with an internal stabilised power supply, it does not manage temporary power losses. The installation of backup equipment with a power rating of 1.5 kW (to be supplied to the load) is strongly recommended.

3.5.2. Instrument Installation Procedure

Connect all the cables, included the monitor and the printer ones, if you want use an external printer. A description of the cabling is outlined in the table shown below.

FUNCTION	CABLE
Power line	Three-pole Bulgin F
Input for printer Output for monitor	Centronics (25 pole M -37 AMP M)
Power line, monitor	Three-pole Bulgin M
Input for keyboard	Multipole shielded

3.5.3. Fuses

Four external protection fuses are inserted into the switch assembly: 3.15A.

3.5.4. Accessories

The ECHO accessories are indispensable parts for the instrument working; the instrument needs, for its operation, to be connected with two external tanks; one contains the liquid for the hydraulics filling and the other is used to contain the waste liquids.

The connection between tanks and instrument is described on the next section.

3.5.4.1. Tanks

To install the waste tank, insert the waste tube coming from the peristaltic pump positioned on the right side of the instrument (fig. 3.2), into the 1000 ml waste bottle, furnished with the instrument.

fig. 3.2

Position the bottle of 500 ml containing the washing solution (our code E/LV01) on its seat, on the right of the diluter module, introduce the tube coming from the diluter valve into the bottle.

Make sure that the tube of the peristaltic pump is inserted and the rotor is well tight.

3.6. Software Installation

The ECHO software is installed and configured by specialized personnel, to assure an optimal working of the analysis system.

3.6.1. Requirements and Recommendations

The ECHO software is optimized to work with this instrument and it uses in the best way its potentialities.

4. THEORY of OPERATION

4.1. Abstract

ECHO is an automatic multi-parameter analyzer for Clinical Chemistry developed for medium or small size labs. This equipment allows to work in "batch mode" or in Urgency procedure, reaching its maximum productivity (180 tests/ hour) with the optimized batch procedure. The ECHO can store 64 methods located in two different panels and each method can use until 3 different reagents. It is possible to set 16 different profiles from these methods. The instrument performs the test repetitions and dilutions automatically or according to the operator choices.

The Instrument can perform, with automatic processes, the following basic operations:

- Reagent distribution process;
- Incubation control;
- Photometric reading process;
- Data analysis evaluation process;
- Analysis results printout process.

All the above mentioned tasks can be fully automated and software controlled reducing time and human resources and assuring a final quality level result free from accidental errors due to the human routine action tolerance.

Each task is executed using both electromechanical devices (such as stepper motors, pumps, valves, etc.) and electronics part (such as active and passive components, micro controller and microprocessors, and so on) including software programs.

The ECHO also includes an electronic photometer working on 340-700nm range that represents the basic instrument for the automatic reading of the analysis results and for controls evaluation.

WARNING

All working procedures must be validated on the analyser before carrying out every laboratory routine.

These procedures are normally validated by the distributor: if the required data are not available for any particular assay, the user must validate these procedures himself.

Any modification to pre-validated routine must be validated again.

The main topics of the ECHO instrument are the following:

- Up to 27 positions for reagent bottles;
- Up to 64 seats for sample vials;
- 96 positions for incubation tubes.
- 1 flow cell for reading is available;
- Urgent Access capability;
- Adaptability to a wide variety of tests available on the market;
- Result data evaluation through proved interpolation methods;

4.2. Principle of Working

The ECHO executes programmed tests in the following two manners: with optimised times, *Batch Mode*, for all the patients; *Urgent Patients*, one by one.

For the *Batch Mode*, the ECHO is working according to the following principles: every cycle is composed of a complete wheel (96 wells). For every cycle it is possible to insert up to 96 wells. Including also the first well for the blank reagent of each method, a well for each standard, a well for each control and a well for each test.

For each test you can programme 27 reagents, the tests with 2 reagents will take 2 places.

Each method is executed completely in one cycle (the maximum per method is of 64 sample / test).

The cycle is programmed for methods that don't use more than 96 wells. The methods over this limit will be executed in the successive cycle.

At the end of execution, the ECHO will sign it with 3 bips and will come back to the execution menu to ask for the next cycle, until the execution of all the programmed test.

During the cycle, the end point methods, including the bi-chromatic ones, are distributed for first and will be measured at the end of the incubation time.

During this interval, the Fixed Time methods, kinetics and differentials are executed. The ECHO will begin the sampling of the tests of one method, waiting the incubation time. When the incubation is terminated, the instrument continues alternatively with a reading of the incubated sample and doing a new sampling.

If the cycle is composed only by End Point methods, the same operational mode is used to increase the execution as much as possible. When a method has done all the samplings, the memorized number of washings will be done.

At the beginning of each cycle, an auto zero procedure is executed.

A washing is executed at the beginning and at the end of each cycle.

For the *Urgent Patients*, the ECHO is working according to the following principles:

Only the patients signed as Urgent will be taken in consideration. The ECHO will execute one patient at a time, for all the methods with a maximum of 27 reagents.

At the end of a patient, the instrument will sing with 3 bips, the operator can verify the reagents and the sampling and can initiate a new execution.

The principles are the same as the ones described in the Batch mode.

For the successive patients the initial washings and the auto zero procedure are not effected.

The blank reagent is executed only for the first patient on whom the method was programmed.

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5. FUNCTIONS

5.1. Intended Use

The ECHO is an analyser designed to automate Clinical Chemistry tests.

The ECHO is designed to automate a great part of operations of the long and borings laboratory routine analysis. It ensures more accuracy and precision of the output, more productivity and more safety for the operator. In this way ECHO assures saving of time and money.

In addition to the traditional in-vitro diagnostic testing, that includes hormones, drugs of abuse, etc., this instrument can be used for a great number of other different applications.

The use of the instrument for some of the mentioned application (e.g. blood screening) may require, in same countries, the approval or registration from Government Agencies.

5.2. Instrument Functions Overview

The ECHO is a fully automated, open system that can process most Clinical Chemistry tests. All operations are automatic and programmable:

- Manual patient sample entry.
- Reagent distribution.
- Incubation (from room temperature to 42°C in the incubation plate).
- Washing.
- Reading.
- Data analysis and printout.

The ECHO has the following important features:

HARDWARE

ECHO has the following features:

- It is an open system that will not restrict the customer to anyone reagent supplier.
- Carry-over between samples is eliminated tanks to an optimized washing procedure.
- It has a photometric station allowing precise and rapid reading of absorbance for each test.

SOFTWARE

The software is an easy-to-use management system with an interactive communication between the operator and the system.

The use of this type of software, simply to use, allows the operator to perform precision testing with minimal computer training.

Additional features of the software include:

- Easy access to menus.
- Easy, step by step programming.
- Fast and accurate printout of test results.
- Reduces the risk of human error.

5.3. Functional Subassemblies

The ECHO is based on the following functional subassemblies:

- Pipetting subassembly
- Flow cell
- Spectrophotometric reading subassembly

The subassemblies are described in the following sections.

5.3.1. Working Area

The working area (fig. 5.1) contains:

fig. 5.1

- Sample rack: primary tube location.
- Reagent rack for 27 standards tanks.

5.3.1.1. Reagent Plate

This plate is located on the left side of the working area end it has 27 positions for the reagent bottles, so it is possible to contemporarily execute a maximum of 27 different methods.

fig. 5.2

5.3.1.2. Sample Plate

This plate (fig. 5.3) is placed in the middle of the instrument working area and it has 64 holes for inserting serum cups with blank samples, standards and controls.

fig. 5.3

5.3.1.3. Reaction Plate

This plate (fig. 5.4) has 4 positions for inserting disposable racks with 24 reaction tubes for each one, so the total capacity is 96 tubes.

fig. 5.4

5.3.2. Pipetting Subassembly

5.3.2.1. Sampling Needle

The mechanical arm with the sampling needle moves on the plates and for each test first picks up the reagents, then takes the serum or standard/control (from the serum cup in the inner plate). Then the needle sends out all the liquid to an incubation tube.

5.3.2.2. Aspiration Needle

After the incubation time, this needle will aspire the liquid from the tube to the flow cell for measurement. A needle performs three aspirations for each test. The first and the second aspiration will not remain in the cuvette and will be transferred to the waste bottle. This will be useful to wash the liquid residues of the previous sample from the fluidic system, avoiding carry-over results. The third aspiration volume will be kept inside the cuvette and measured for the reading time selected by the method. After reading this liquid will be thrown away, thus clearing the flow cell for a new measure.

5.3.2.3. Syringe

The syringe can aspire in two different ways depending to the position of the electro valve located on its top: it can aspire from the water bottle or from the sampling needle. The movements of this component regulate the aspiration and the ejection from the sampling needle and allow cleansing of the tubes and all the fluidic system with distilled water.

5.3.2.4. Peristaltic Pump

The peristaltic pump can perform a number of steps in the third aspiration (reading aspiration) variable from the first and the second one. The number of steps can be modified by user (user parameters) to allow a greater or a lower aspiration in order to reach the exact position of the liquid front in the inlet tube.

5.3.3. Flow Cell

This component is located under the little metal door of the instrument. It has inlet tubes coming from the aspiration needle and outlet tubes that going to the peristaltic pump at the waste bottle.

5.3.4. Spettrophotometric Reading

Photometric reading is performed by a spectrophotometer. The liquid is automatically transported to the reading stations. An internal microprocessor controls the 9selectable interference filters.

The system measures the optical densities (mono or bichromatic reading) of each test.

The principle on which is based the photometric reading is the Lambert-Beer law.

An incident wave, shooting a solution that holds a substance with homogeneous concentration, respects this law through its path inside the solution; the law is expressed by the following formula:

$$I = I_0 \cdot e^{-KdC}$$

where

I_0 ⇨ Shooting wave amplitude.

I ⇨ Transmitted wave amplitude.

$K(\lambda)$ ⇨ Spreading constant of substance (wavelength function).

d ⇨ Wave optical path inside solution.

C ⇨ Substance concentration in solution.

Through use of specific reagents in solution for the substance we want to measure, it's possible to overvalue the spreading constant for a fixed wavelength, so transmitted wave amplitude becomes concentration function:

$$C = \ln\left(\frac{I_0}{I}\right) \cdot \frac{1}{Kd} \qquad \Rightarrow \qquad C \cong \ln\left(\frac{I_0}{I}\right)$$

This relation allows evaluation of substance concentration by measuring of Absorbance:

$$ABS = \ln\left(\frac{I_0}{I}\right) = kdC$$

The measure chain could be represented by the following scheme (fig. 4.1):

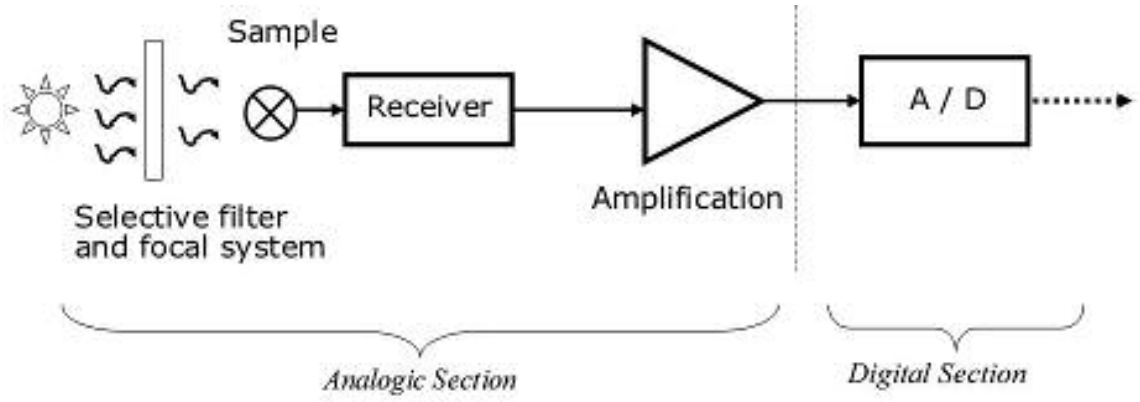


fig. 4.1

5.4. Management System

The ECHO software operates under DOS operative system. A series of menus enables the user to navigate within the programs.

The ECHO software has a list of assay methods pre-programmed by a Technical Support Representative. This protocol list can be easily modified, deleted or even added to, using the information provided with a test kit.

The software is password protected with a defined password, that can be modified only by the authorised user (see the Configuration Section).

5.4.1. Software Architecture

In the following paragraphs are described the main functions of ECHO software, that allow to set, test and use the instrument.

5.4.1.1. Main Menu

The Main menu enables the user to access the five main software features, described in the next paragraphs.

5.4.1.2. Work List

This section allows the user to program the patients database and to set the tests list for each patient.

5.4.1.3. Execution

This option gives the access to the section that allows to start the analysis procedure.

5.4.1.4. Results

This option allows to display, print and send the results report of a test session.

5.4.1.5. Chemistries

This software section is used to edit, modify, print or create new assay procedure.

5.4.1.6. Service

The Service function allows to initiate the calibration procedures. Only specialised personnel have access to this section of the software.

See Service Manual (p/n: ...) for details.

6. PERFORMANCE CRITERIA AND LIMITATIONS

6.1. General Statement

This section provides information on the performance of the instrument that need a peculiar approach to measure them being based on statistic or indirect method measurements.

This paragraph provides the statement for these items.

Precision: It is the concordance between the repeated measures: it gives the ability of the instrument to reproduce the same value when handling the same quantity.

Accuracy: It is the ratio between the expected value of the parameter and the true value.

Linearity: Let us assume that the measured values of an ideal-instrument are on a straight line; the *Linearity* is the shifting from this ideal straight line of the real-instrument measures.

The first photometer precision, accuracy and linearity tests are executed in the O.D. TEST function (F5 SERVICE, F3 DIAGNOSTICS, F2 O.D. TEST) and are necessary to validate the photometer. The pipettor precision, accuracy and carry-over tests are executed running a simplified method and use the photometer as the test instrument to validate the pipettor.

The tests use a kit of four reference solutions of Potassium Bichromate, with the following nominal O.D. at 340 nm wavelength:

- 2000 mAbs
- 1000 mAbs
- 500 mAbs
- 250 mAbs

The solutions are calibrated by the SYSTEA Srl laboratory using a spectrophotometer (UV/VIS JENWAY mod. 6405, accuracy of 0,1%). The real certificated O.D. values of the reference solutions are employed in the tests calculations.

6.2. Photometer

6.2.1. Precision

This test evaluates the repeatability of the reading. It is performed evaluating the CV% of a series of readings of the same solution.

The test is performed repeating n=8 times the reading of a concentrated solution of Potassium Bichromate with an O.D. of 2.000 mAbs at 340 nm wavelength.

After the execution of the eight tests, it is necessary to calculate the CV% :

$$So = \sum ODi \qquad Soo = \sum ODi^2$$

$$Vm = So / n \qquad Voo = (Soo - n\ Vm^2) / (n-1)$$

$$CV\% = \sqrt{Voo} / Vm * 100$$

The acceptance level of the CV% is lower or equal to 2%.

6.2.2. Accuracy

The accuracy test of the photometer is performed together with the precision test, measuring the average O.D. of a reference concentrated solution of Potassium Bichromate with an O.D. of 2.000 mAbs at 340 nm wavelength.

$$So = \sum ODi$$

$$ODm = So / n$$

This value obtained with the instrument in O.D. TEST (F5 SERVICE, F3 DIAGNOSTICS, F2) is compared with the O.D. reference value. The difference between the two values must be lower than 2%.

$$|ODm - ODr| \ / \ ODm \ * \ 100 \ < \ 2$$

6.2.3. Linearity

The linearity test has the purpose to verify the linearity of the optical group (photometer detector plus preamplifier).

The test is performed using the concentrated solution of Potassium Bichromate with a nominal O.D. of 0.250, 0.500, 1.000, 2.000 mAbs at 340 nm wavelength.

The four solutions are read with the instrument in the O.D. test menu (F5 SERVICE, F3 DIAGNOSTICS, F2 O.D. TEST) for direct immediate optical density reading.

The solutions are aspirated directly in the cuvette pulling out the aspiration needle.

After the execution of the four tests, it is necessary to calculate the correlation index:

	1	2	3	4
Concentrations Ci (nominal value)	C1 (0,250)	C2 (0,500)	C3 (1,000)	C4 (2,000)
Opt.Densities ODi	OD1	OD2	OD3	OD4

$Sc = \sum Ci$ $\quad Scc = \sum Ci^2$ $\quad Vcc = n\ Scc - Sc^2$

$So = \sum ODi$ $\quad Soo = \sum ODi^2$ $\quad Voo = n\ Soo - So^2$

$Sco = \sum (Ci \cdot ODi)$ $\quad Voc = n\ Sco - Sc\ So$

Correlation index $R = Voc / \sqrt{(Vcc \cdot Voo)}$

To accept the test, the correlation index must be higher or equal to 0,95.

NOTE: The linearity and the correlation index can be calculated automatically and the graph can be printed using the instrument's curve calculations.

A special user test must be edited with:

- **N. of standards: 4 (or 8 if the solutions are read twice)**
- **Calculation mode: linear regression**
- **Curve values (O.D. and std values) taken from the test results**

6.3. Pipettor

6.3.1. Precision

This test evaluates the repeatability of the reading of a concentrated solution dispensed through the ECHO pipettor. It is performed evaluating the CV% of a series of readings of the same solution and compared with the CV% of the photometer obtained with test #1.

It is necessary to prepare a special test method:

- type: end-point,
- sample volume: 100
- reagent volume: 400
- reagent position: 1
- incubation time: 0 sec

The test is performed repeating n=8 times the reading of the concentrated solution of Potassium Bichromate with O.D. 2.000 mAbs at 340 nm wavelength. The concentrated solution is put in the first 8 sample cups (1 – 8) and distilled water is put in reagent position 1.

After the execution of the eight tests, it is necessary to calculate the CV% :

$$So = \sum ODi \qquad Soo = \sum ODi^2$$

$$Vm = So / n \qquad Voo = (Soo - n\,Vm^2) / (n-1)$$

$$CV\% = \sqrt{Voo} / Vm \cdot 100$$

The acceptance level of the CV% is lower or equal to 5%.

6.3.2. Accuracy

The test is performed comparing the O.D. obtained diluting the reference solution with the instrument's pipettor and the O.D. obtained diluting the reference solution with a manual pipettor.

It is necessary to prepare four samples using the automatic samples dilution function and four samples with no dilution programmed, but already diluted with a manual pipettor:

first program: F1 WORKLIST, F1 INSER.WORK-LIST,

then execute: F2 EXECUTION, F3 AUTOMATIC SAMPLES DILUTION)

The 4 + 4 solutions are read as the previous test #2 (photometer accuracy test).

ODp = optical densities with automatic pipetting

ODr = optical densities with manual reference pipetting

$$ODpm = \sum ODp / n$$

$$ODrm = \sum ODr / n$$

The two values obtained with the instrument in O.D. TEST (F5 SERVICE, F3 DIAGNOSTICS, F2) are compared. The difference between the two values must be lower than 4%.

$$|ODpm - ODrm| / ODrm \cdot 100 < 2$$

6.4. Carry-Over

This test aims to verify the contamination between a highly concentrated sample and three following null concentrated samples.

The test is performed using the Potassium Bichromate solution with an O.D. of 2.000 mAbs at 340 nm wavelength in sample position 1 and three tubes of distilled water in sample positions 2, 3 and 4.

It is necessary to prepare a special test method:

- type: end-point,
- sample volume: 250 µl
- reagent volume: 250 µl
- reagent position: 1
- incubation time: 0 sec

Running the four tests, it is requested that the O.D. of the first blank sample is lower than 20 mAbs (1% of the concentrated solution).

In case of failure, the O.D. of the two following water samples gives an index of the carry-over progression over several samples.

7. OPERATING PROCEDURES

7.1. Preparation Prior Operations

In the following paragraph are quoted the necessary information that the user must know for a correct use of the instrument.

The information about sample handling, reagents and disposable materials are general; it is recommended to read the respective Manufacturer guides.

7.1.1. Safety Recommendations and Remarks

Read carefully the Safety section for detailed safety instructions.

To reduce risks it is important to follow the safety precautions listed in Section 2.

The Instrument Calibration, the Setting and the Adjustments of the instrument should be carried out by Technical Support Personnel only.

7.1.1.1. User Skill Level

User appointed for instrument operations must have a good technical skill in medical In Vitro Diagnostic (IVD) analysis; as highlighted in the Safety section, the use of Good Laboratory Practice is mandatory to get the proper level of safety when the instrument is used for medical in-vitro diagnostic use.

It is very important that the user must know the details of the 'User's Manual': additionally he needs to be trained, according to the manufacturing procedures, to the use of the instrument for operations.

The user can't approach to the software's sections protected from passwords out of his competence.

7.1.2. Instrument Set-up

Switch on the instrument; on the screen will appear the message (fig. 7.1.1):

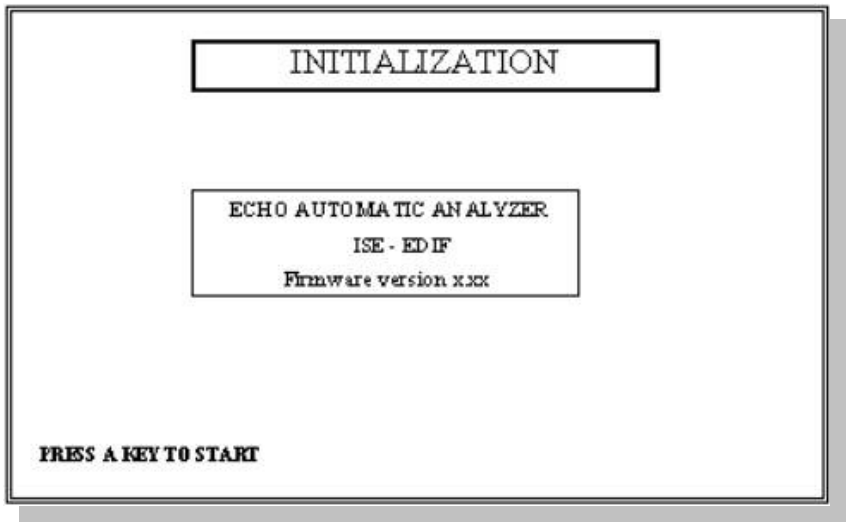


fig. 7.1.1

Press a key and wait until the initialization is performed. It controls the correct functioning of the principal instrument subassemblies. In case of malfunction will appear an error message on the screen.

Prior to load the materials required for the instrument run, consisting in reagents, test supports, samples, etc., carry out the following steps:

- Empty the waste tank: this must be usually performed on instrument shut down.
- Check that tanks for the distilled water are filled.

7.1.2.1. Instrument Built-in On Line Test

The self-test of the instrument is performed automatically at the instrument start-up.

7.1.3. Sample Handling

To ensure a correct use of the instrument and to increase the reliability level of the analysis results it is important to read the following information.

Samples preparation: samples must be adequately brought to room temperature and checked to be free from clot, fibrin, froth or bubbles. The presence of clot and fibrin may cause incorrect dispensation of sample.

NOTE: The information about Sample quoted in this is general. We strongly recommend to read carefully the instruction of the assay Manufacturers.

WARNING

In case that the ECHO is used for fully automated medical In Vitro Diagnostic (IVD) analysis, the Manufacturer remind to the Users that failures to follow correct sample handling procedures could produce false negative results reporting.

7.1.3.1. Sample Type

ECHO can be used for fully automated in vitro diagnostic analysis, utilizing samples like blood, serum, plasma, urine and any liquid solution coming from a sample preparation.

NOTE: it must be validated that the pipetting system is able to handle the viscosity of the liquids loaded as samples when they are resulting from a sample treatment/preparation.

7.1.3.2. Pre-treatment

To avoid 'in vitro' alterations that could modify analysis result, the sample must be preserved according to specific reagent manufacturer instructions.

7.1.3.3. Preservation

To avoid 'in vitro' alterations that could modify analysis result, the sample must be preserved according to specific reagent manufacturer instructions.

The general instructions to preserve samples are the following:

Serum or plasma: centrifugate the vial with the blood (after coagulation in case of serum); put serum or plasma in another vial and refrigerate till the test.

Urine: prepare a sample in a 10 ml vial and refrigerate till the test.

7.1.3.4. Sample Minimum Volume

It is the dead volume plus the volume needed to carry out the analysis.

7.1.3.5. Dead Volume

If the sample volume is less (or equal) than dead volume, the needle can't aspirate it. The sample dead volume for standard tubes is <100µl: this may be reduced using vials with conical shape at the bottom. They need to be properly calibrated by Technical Service personnel.

7.1.4. Reagent and Disposable Materials

Reagents are the materials that, interacting with sera, generate the reaction at the various step of the procedure. The reading of the final colour supplies the analysis outcome.

Disposable materials are vials and disposable needle cleaning filters.

Reagent can be loaded in polystyrene tubes 24 ml. It is recommended to not reuse reagent vials.

NOTE: The information about Reagents and Disposable Materials quoted in this is general. We strongly recommend to read carefully the instruction of their Manufacturers.

7.1.4.1. Use

Preparing the reagents before or during the test procedure, depending on their stability. Reagents and samples should be at room temperature (18÷25°C) before beginning the assay and can remain at room temperature during testing. All containers used for preparation of reagents must be cleaned thoroughly and rinsed with water before use.

Preparation of reagents and controls: these must be free from froth or bubbles on the surface of the liquid or inside the test tubes or vials.

Use only disposable needle cleaning filter of the manufacturer's specified type.

7.1.4.2. Preservation

To preserve reagents and disposable material user must follow carefully manufacturer instruction.

7.1.5. Fixture and Accessories

For the list and the description of ECHO accessories see Chapter 3.

7.2. Management System Overview

The ECHO software runs with DOS operative system, and it is simple to use. The system is provided with pre-validated test procedures; these procedures can be modified, added or deleted in easy way.

The software is protected by passwords, that only authorized personnel can modify.

7.2.1. How to Start

After the initialization procedure, the ECHO will ask for an analyst ID number (0-4). Analyst #0 has full access to the system while analysts #1 to #4 have restricted access to:

- *Edit Methods* ⇨ Read mode only.
- *Edit Profiles* ⇨ Read mode only.
- *Load / Dump* methods ⇨ No access.
- *Copy / Swap* methods ⇨ No access.
- *Edit Parameters* ⇨ No access.
- *Laboratory Data* ⇨ No access.

After the analyst number, the ECHO will ask for a password. It can be alpha-numeric and can have up to 6 characters.

If no password is stored, ECHO will ask to insert a new password (***Insert new***).

The standard password memorized as default is 000000 (6 times 0).

Access to the instrument is denied until a valid password is typed.

The master analyst (#0) can access to the Laboratory Data, where are recorded two lines for the Laboratory Header printing and the five Analyst names.

Blanking an analyst name will disable that analyst and clear the related password. Analyst #0 cannot know the password of the other analysts, but can only cancel them. With the ECHO numeric keyboard, the analyst name can be canceled with the *CLEAR* / *FEED* key.

If the master analyst has forgotten his password, after typing a wrong password for analyst #0, the ECHO will display a key number and wait for a master password. The master analyst must call the assistance, give the key number and get back the master password. This master password will clear Analyst #0 password and give access to the instrument only once.

The *TEST TOTALS* displayed in the *CONTROLS* menu are, in release 3.xx separated per analyst. The values displayed are only the tests executed by the selected analyst. Anlyst #0 can display the totals for all the analysts.

7.2.2. Main Menu

Once user has type his password (fig. 7.1.1), will be displayed the following screen (fig. 7.2.1):

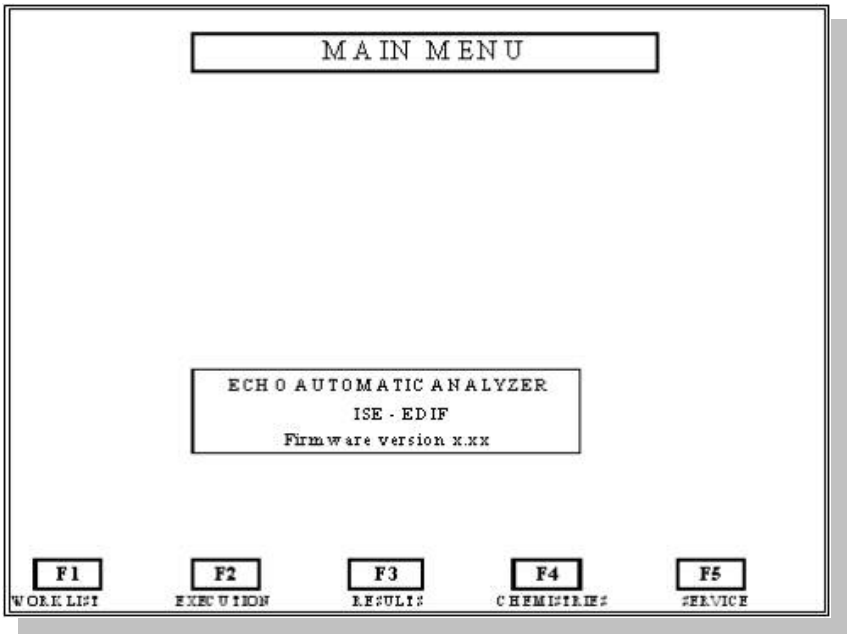


fig. 7.2.1

From this screen is possible to have access to the five main software sections, by pressing the corresponding key:

F1 WORK-LIST	Allows the access to the patients manager section.
F2 EXECUTION	Allows to run the assay procedures.
F3 RESULTS	This button gives the access to the result section.
F4 CHEMISTRIES	The Chemistries section allows to edit, modify, print a chemistry method or to set up a new method.
F5 SERVICE	The service section access is reserved to authorized personnel only.

7.3. Chemistries Menu

In this section is detailed the procedure to modify the parameters of a test section.

From the *Main menu* (fig. 7.2.1) press the **F4** button; the following window will be displayed (fig. 7.3.1):

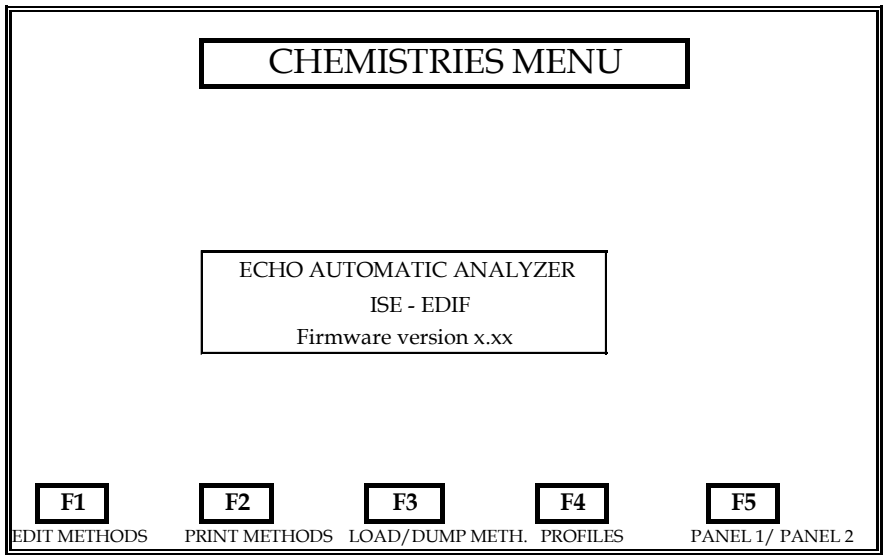


fig. 7.3.1.

From this screen is possible to have access to the following six sections, pressing the corresponding key:

F1
Edit Methods

Allows to edits the methodologies.

F2
Print Methods

Allows to print the tests methodologies.

F3
Load/Dump

This button allows to import methods from an external PC.

F4
Profiles

To enter in the *Profiles* menu.

F5
Panel 1/2

To select *Panel 1* (Clinic chemistries) or *Panel 2* (Turbidimetry), with 32 tests each one.

7.3.1. Edit Methods

To enter in the Edith Methods menu, press the **F1** button in fig (7.3.1), the following screen will be showed (fig. 7.3.2):

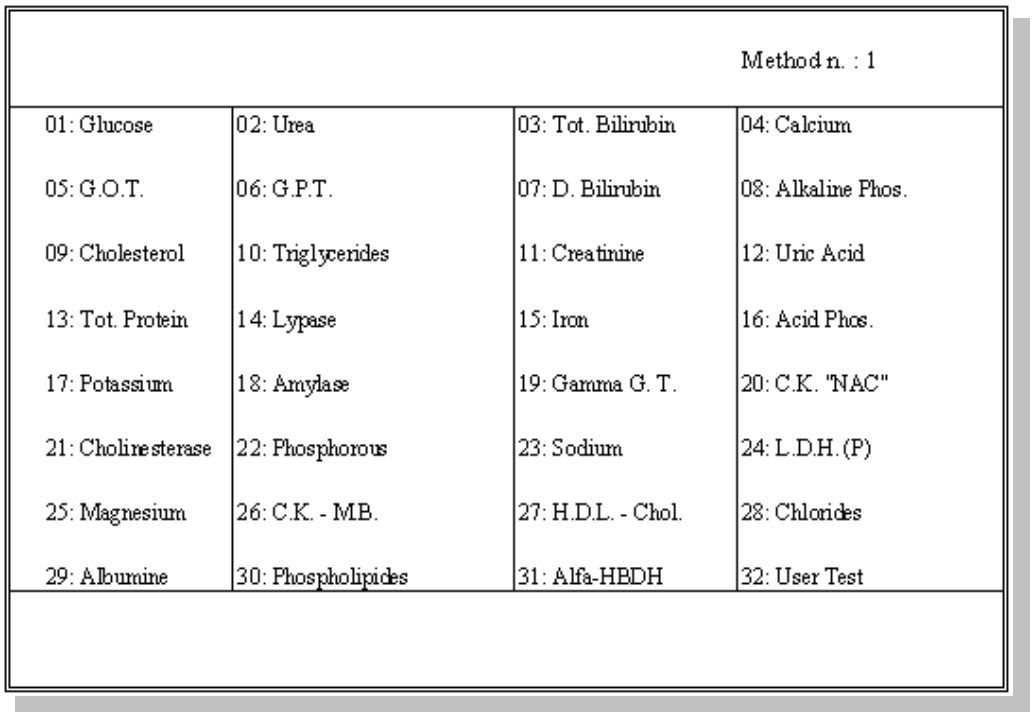


fig. 7.3.2

Now select a method typing its code from 01 to 32 (ex.: 02 to select *Urea*); will be showed the following window, with all the selected test parameters (fig. 7.3.3):

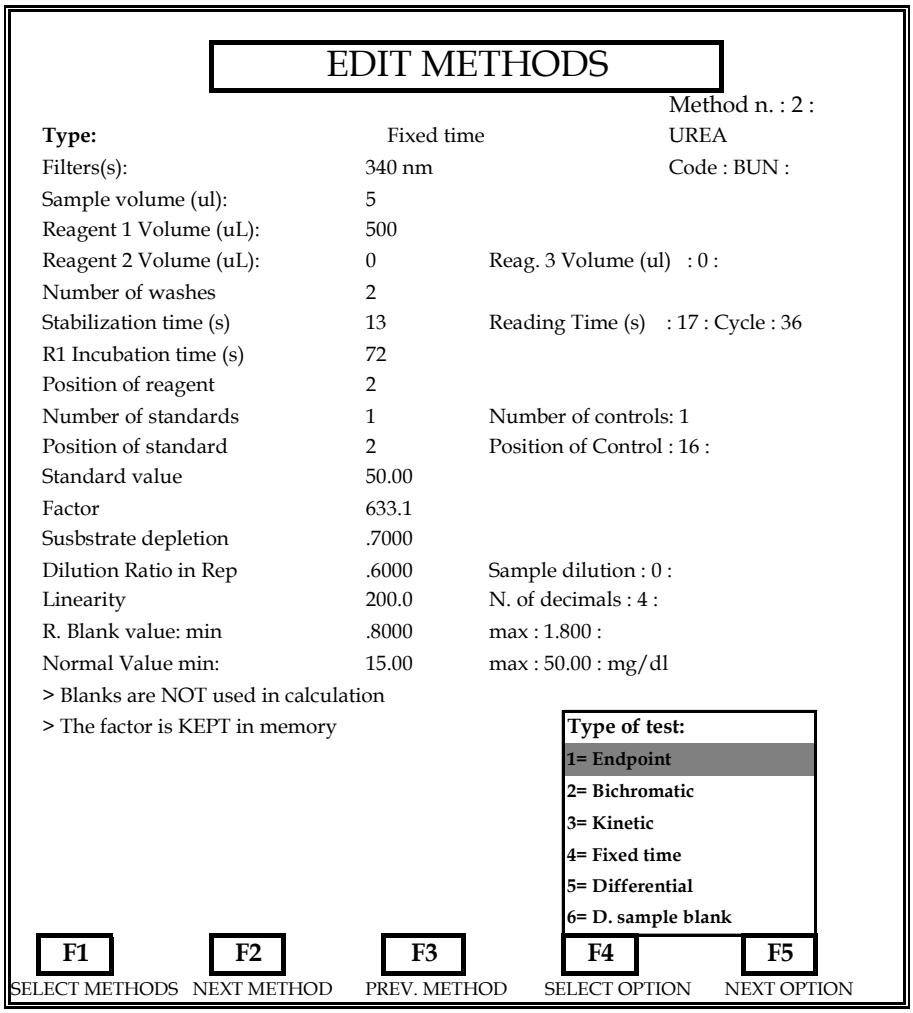

EDIT METHODS
Method n. : 2 :
Type: Fixed time UREA
Filters(s): 340 nm Code : BUN :
Sample volume (ul): 5
Reagent 1 Volume (uL): 500
Reagent 2 Volume (uL): 0 Reag. 3 Volume (ul) : 0 :
Number of washes 2
Stabilization time (s) 13 Reading Time (s) : 17 : Cycle : 36
R1 Incubation time (s) 72
Position of reagent 2
Number of standards 1 Number of controls: 1
Position of standard 2 Position of Control : 16 :
Standard value 50.00
Factor 633.1
Susbstrate depletion .7000
Dilution Ratio in Rep .6000 Sample dilution : 0 :
Linearity 200.0 N. of decimals : 4 :
R. Blank value: min .8000 max : 1.800 :
Normal Value min: 15.00 max : 50.00 : mg/dl
> Blanks are NOT used in calculation
> The factor is KEPT in memory
Type of test:
1= Endpoint
2= Bichromatic
3= Kinetic
4= Fixed time
5= Differential
6= D. sample blank
F1 SELECT METHODS
F2 NEXT METHOD
F3 PREV. METHOD
F4 SELECT OPTION
F5 NEXT OPTION

fig. 7.3.3

The position of the cursor indicates if a parameter is opened for modification or not.

Note: The 5 parameters indicated by ⇒ are opened by a sub-menu selection in a window on the right side of the screen, that appears when the cursor is positioned on one of the parameters.

The parameters are detailed in the following sections.

To exit from the *Edit Methods* menu, press the **PgUp** button or the **Esc** button, then press **F1** to not save the modifications or **F2** to save the modifications.

To print the chemistries, press the **F2** button from the *Chemistries Menu* (fig. 7.3.1).

7.3.1.1. Types Selection

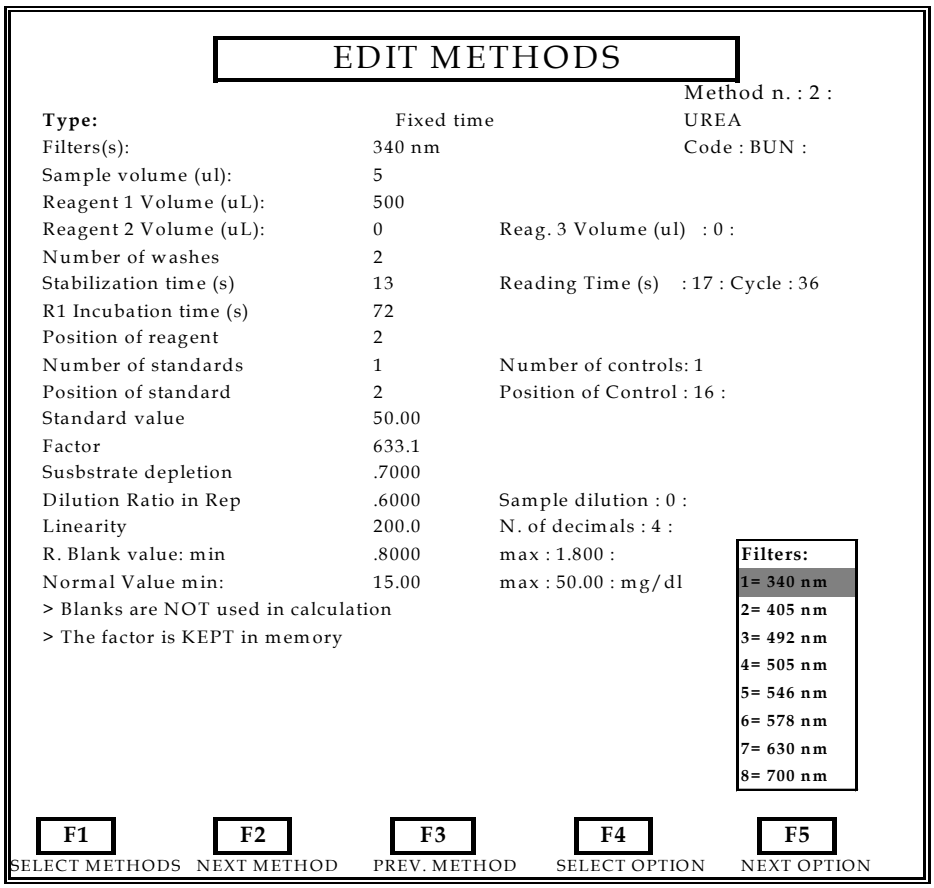
Use the **F4** and **F5** buttons to go to the next/previous option. The keys from **1** to **9** of the keyboard, select directly the correspondent option.

In fig. 7.3.3 in the ***Type*** field, is possible to change the name of the method (max. 15 characters) and the code number (max. 3 characters); place the cursor in the field and press two time the '**.**' button. The available types are:

- End point.
- Bichromatic.
- Kinetics.
- Fixed time.
- Differential.
- Differential, with blank reagent.

7.3.1.2. Filter Selection

In the ***Filters*** field (fig. 7.3.4) is possible to set the photometer filter. The available filters will appear in a window on the right of the screen; in case of bi-chromatic methods, the program will ask for a second filter. The ECHO has 10 filter positions: the position 0 is f or the offset readings.



Note: In case of Bichromatic analysis the instrument will ask you to memorize a second filter.

7.3.1.3. Incubation Time

Range: 12 – 9999 seconds.

This represent the foreseen time of the reaction. This is the time between the sampling and reading. The software can modify this time in a small range, adapting it to the cycle of the instrument.

For the methods with 2 reagents, this time (minimum) is the one between the sampling of the first and second reagent.

7.3.1.4. Stabilization Time

Range: 1 – 60 seconds.

It is the time between the pipetting in the measure cuvette and the reading. This time is necessary to allow the thermo-stabilization and turbulences stabilization.

7.3.1.5. Reading Time

Range: 1 – 254 seconds.

This is the measure time. The sampling A/D converter has a frequency of 200 m/sec. The sum of the readings during the measure time gives the result.

7.3.1.6. Reagent 2 – Incubation Time

Range: 12 – 9999 seconds.

Set this value different from 0, if method works with two reagents (end point, bi-chromatic, kinetics or fixed time). It is the time between the pipetting of the reagent 2 and its reading. In case of *Incubation Time* this is the distribution time between the reagent 1 and reagent 2.

7.3.1.7. Reagent Position

Range: 1 – 27.

It is the position of each reagent assigned by the user. ECHO has 27 positions for the reagents, and can work on 27 mono reagents methods for each plate. The methods with 2 reagents are using 2 consecutive positions, reducing in this way the number of simultaneous methods in use.

The user should assign 32 positions to reagents in two test groups (table 1 / table 2). We suggest to assign in each group an exclusive positions for the most frequent and usual tests, and to reserve the other positions for the rare methods or to the other tests which are rarely simultaneous.

If there are two application with the same position in use, the analyzer will change the position of the method with the major incubation time.

7.3.1.8. R1 Reagent Volume (µl)

Range: 5 – 800.

Typical: 400 – 500.

It is the reagent volume (in micro liters).

7.3.1.9. R2 Reagent Volume (µl)

Range: 5 – 800.

Typical: 5 – 50.

It is the second reagent (in micro liters). This value must be set to 0 for the mono-reagent methods. A value different from 0 indicates a method with 2 reagents.

7.3.1.10. R3 Reagent Volume (µl)

Range: 5 – 800.

Typical: 5 – 50.

7.3.1.11. Sample Volume

Range : 5 – 500.

It is the sample volume (in micro liters).

7.3.1.12. Numbers of Calibration Standards

Range: 0 – 8.

This value indicates the number of standards used for the calibration.

0: Value calculated with a factor. A missing factor will cause an error.

1: If the value of the factor is 0, during the analysis cycle the ECHO will measure the optical density of the standard sample, from the beginning of the test executions and will calculate the factor. The factor will be positioned in standard position and will have a defined value (standard value).

From 2 to 8: These values are used for non linear methods (immunology). In this case the ECHO will calculate with the number of curves and the description of the curve. The length of the curve is equal to the number of the standard; this should be positioned in increasing order, starting form the position defined by the standard position.

See also the *Standardization Procedure* (Par. 7.4.1.2).

7.3.1.13. Numbers of Controls

Range: 0 – 3.

The ECHO allows to store up to 30 values of control for each method on one level. The control should be requested by the user during the execution time (see tests and controls to execute). If this parameter is '0', you can not execute or memorise any control. If this parameter is '1', a control will be executed at the beginning of the execution of the corresponding methods, immediately after this a possible standard. The control sample should be placed in the position defined by the 14 parameter (control of position).

7.3.1.14. Standard Position

Range: 1 – 16

1 – 15 with 1 control

1 – 14 with 2 controls

1 – 13 with 3 control...

These are the positions from 1 to 16 in which the user should place the standards in case of mono standard methods.

This is the start position from 1 to 16 in which the user should position the standard samples defined by the 11 parameter (standard number) in case of multi-standard methods.

The standards should be placed in side by side increasing positions.

If the last standard position is over the position 16, this will cause an error.

7.3.1.15. Control Position

Range: 1 – 16.

This is the position, where the user should place the controls. See parameter 12 (number of controls).

7.3.1.16. Standard Value

Range: 0.000 – 99999.

This parameter will appear only when the number of standards is '1'. This is the theoric value of the standard used in case of mono standard methods. A null value will cause an error; when the factor is '0' is necessary to evaluate a new standard.

7.3.1.17. Factor

Range: 0.000 – 99999.

This parameter will appear only when the number of standard is minor or equal to 1. For the mono standard or with no standard methods, the factor value is multiply for the optical density to have a result.

The user should insert the factor, in case of methods without standard.

7.3.1.18. Description of the Curve

This parameter appears only when the number of standards is greater than 1. This multiple parameter permits the visualization of the values curve: the upper line is the Y coordinate (O.D.), the inferior line is the X coordinate (Val. Std.).

The curve has as many points as many number of standards has been defined in the parameter 11. The result is calculated with the Cubic spline interpolation.

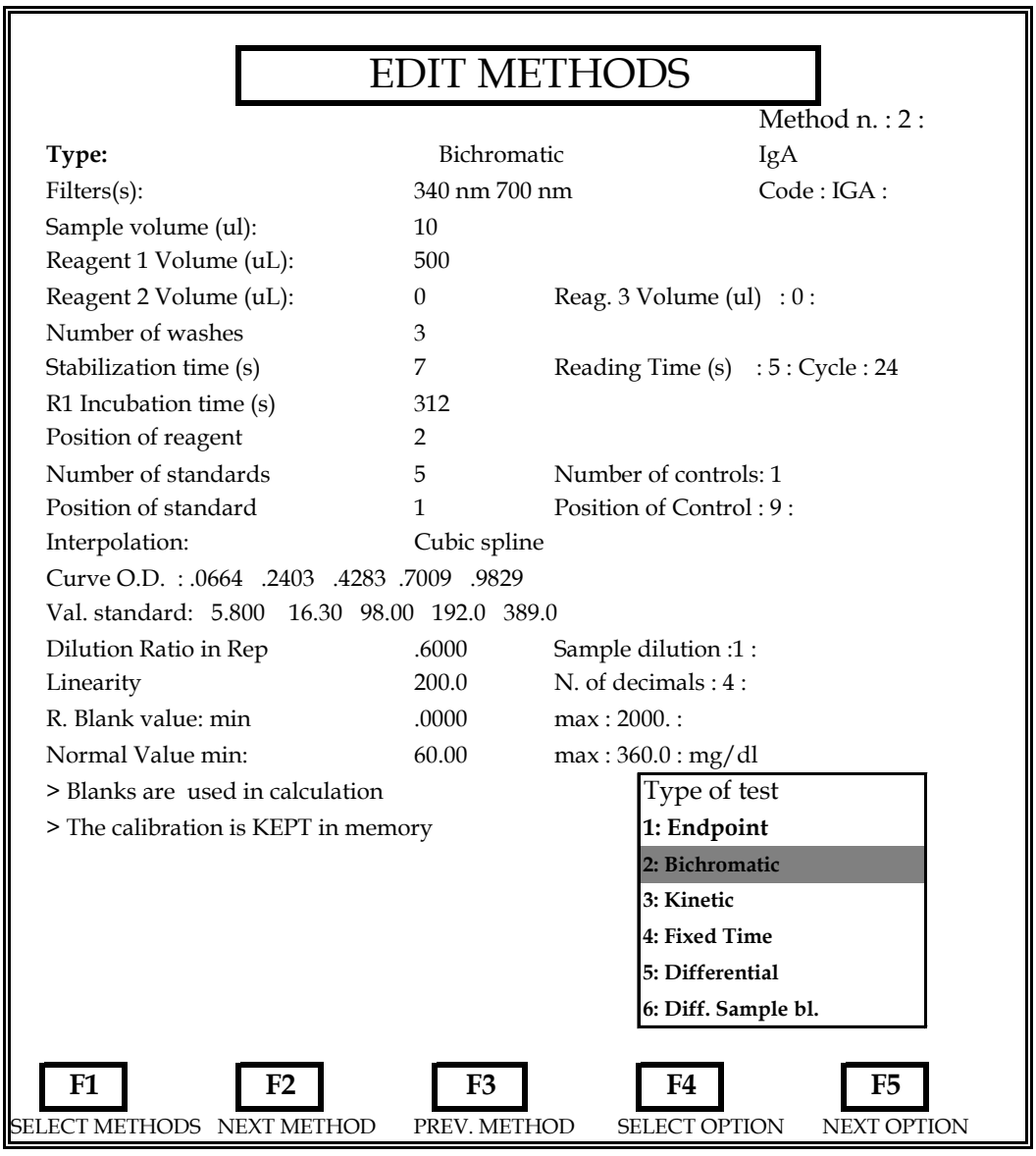

EDIT METHODS
Method n. : 2 :
Type: Bichromatic IgA
Filters(s): 340 nm 700 nm Code : IGA :
Sample volume (ul): 10
Reagent 1 Volume (uL): 500
Reagent 2 Volume (uL): 0 Reag. 3 Volume (ul) : 0 :
Number of washes 3
Stabilization time (s) 7 Reading Time (s) : 5 : Cycle : 24
R1 Incubation time (s) 312
Position of reagent 2
Number of standards 5 Number of controls: 1
Position of standard 1 Position of Control : 9 :
Interpolation: Cubic spline
Curve O.D. : .0664 .2403 .4283 .7009 .9829
Val. standard: 5.800 16.30 98.00 192.0 389.0
Dilution Ratio in Rep .6000 Sample dilution :1 :
Linearity 200.0 N. of decimals : 4 :
R. Blank value: min .0000 max : 2000. :
Normal Value min: 60.00 max : 360.0 : mg/dl
> Blanks are used in calculation
> The calibration is KEPT in memory
Type of test
1: Endpoint
2: Bichromatic
3: Kinetic
4: Fixed Time
5: Differential
6: Diff. Sample bl.
F1 SELECT METHODS
F2 NEXT METHOD
F3 PREV. METHOD
F4 SELECT OPTION
F5 NEXT OPTION

fig. 7.3.5

7.3.1.19. Substrat depletion

Range: 0.000 – 99999.

This parameter is used only kinetic and fixed time type methods.

If the difference between the optical density of the first reading and the optical density of the blank reagent is greater than the value of the substrat depletion, the following message will appear: **S*ubstrat depletion.*** .

7.3.1.20. Dilution Ratio

Range: Max 1.0 (typical 0.5 – 0.25).

When at the end of a cycle, is requested a repetition of a test with an automatic dilution, the sample volume is multiplicated by the dilution ratio and the reagent volume is increased to compensate the reduction of the sample volume.

Sample vol. x *dilution ratio*

Reagent vol. + *Sample vol.* x (1 – *dilution ratio*)

NOTE: it is not possible to use sample volumes after dilution inferior to 3 micro litres.

7.3.1.20. bis Sample dilution

It is possible to pre-dilute the sample in case of patients with chronicle diseases (for example diabetes) or for the determination of the Creatinuria.

This dilution is done with the physiological solution or distilled water. The function has three options:

0	Does not accept pre – dilutions
1	Accepts the pre-dilution and the result is not treated mathematically (for ex. Pre-diluted at 50 % the final result will at 50%)
2	Accepts the dilution and the result is treated mathematically (for exp. Pre-diluted at 50 % the final result will be calculated multiplying by 2)

7.3.1.21. Linearity

Range: 0.000 – 99999.

If the result is greater than this value, the following message will appear: ***Not linear result.***

The test should be repeated with the diluted sample (see repetitions).

7.3.1.22. Reagent blank value: min

Range: 0.000 – 99999.

If the optical density of the blank reagent is minor to the value determined by this parameter, the following message will appear: ***Blank out of range.***

7.3.1.23. Reagent blank value: max

Range: 0.000 – 99999.

If the optical density of the blank reagent is greater than the value determined by this parameter, the following message will appear: ***Blank out of range.***

7.3.1.24. Normal Value: min

Range: 0.000 – 99999.

If the result of a test is minor to the value determined by this parameter, on the screen, after the value, the ***L*** symbol will appear.

7.3.1.25. Normal Value: max

If the result of a test is greater than the value determined by this parameter, on the screen, after the value, the ***H*** symbol will appear.

7.3.1.26. Measure Unit Selection

Is possible to choose the result measure unit; select the appropriate one from the windows that appear on the screen (fig. 7.3.6).

Use **F4** button to select the option and **F5** button to go to next option.

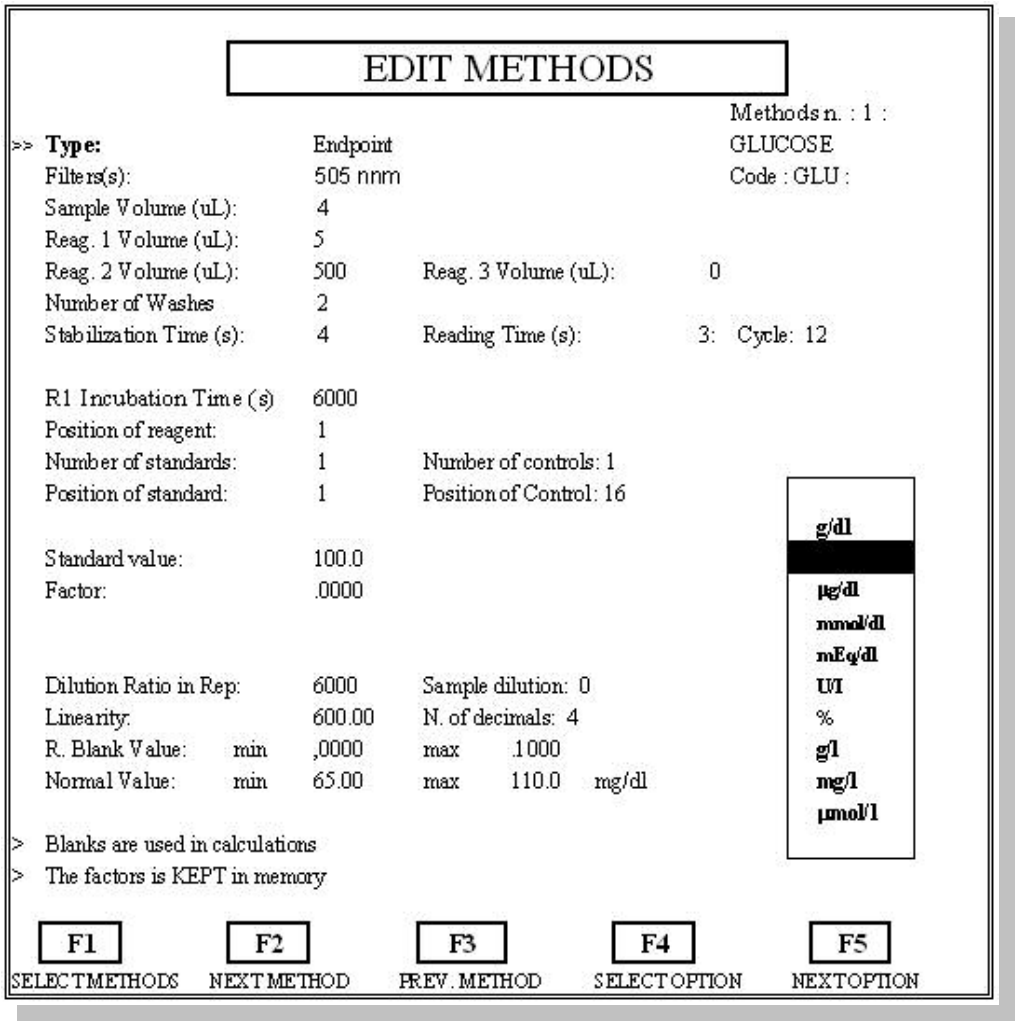


fig. 7.3.6

7.3.1.27. Washings Number

Range: 1 – 13 (typical 2).

For the high density reagents use 3 or 4. For creatinine, iron, calcium use 5. This is the number of the vials and syringe washing, carried out after the sampling, and the number of washings of the flow cell carried out at the end of the measure. For the last washings instrument uses 1000 micro liters of distilled water, while for the others it uses 500 micro liters.

7.3.1.28. Blank Reagent Selection

Is possible to choose between two options (see fig. 7.3.7):

1: NOT USED in calculations

2: be USED in calculations

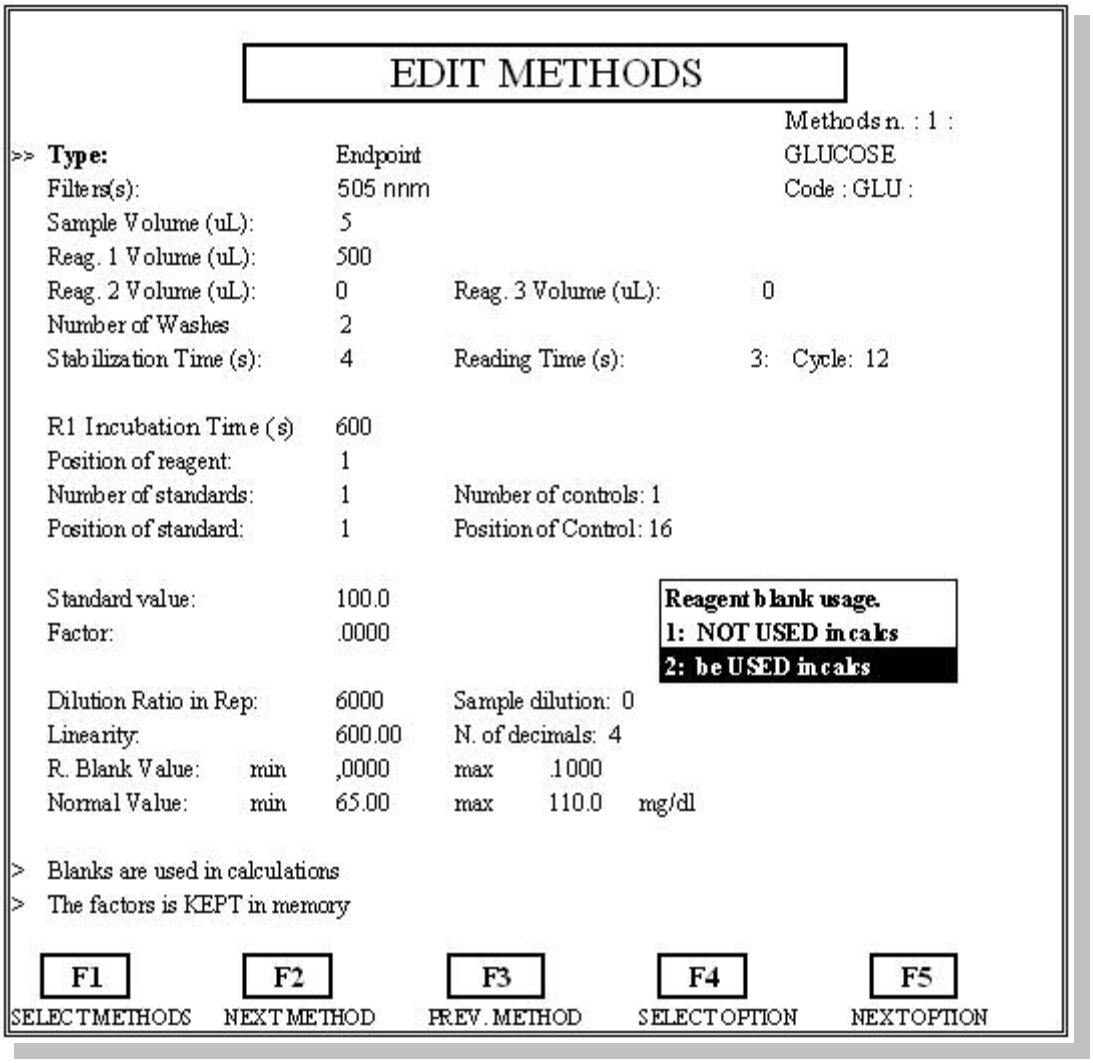


fig. 7.3.7

In fact during the calculations, ECHO can compare or not compare the optical density of the blank reagent with the optical density of the sample. In any case a test with the blank reagent will be executed to check the reagent quality. Typically the end point (bi-chromatic and differential) uses the blank reagent.

7.3.1.29. Factors and Curves Selection

Is possible to choose between two options (see fig. 7.3.8):

1: ERASED daily

2: values are KEPT

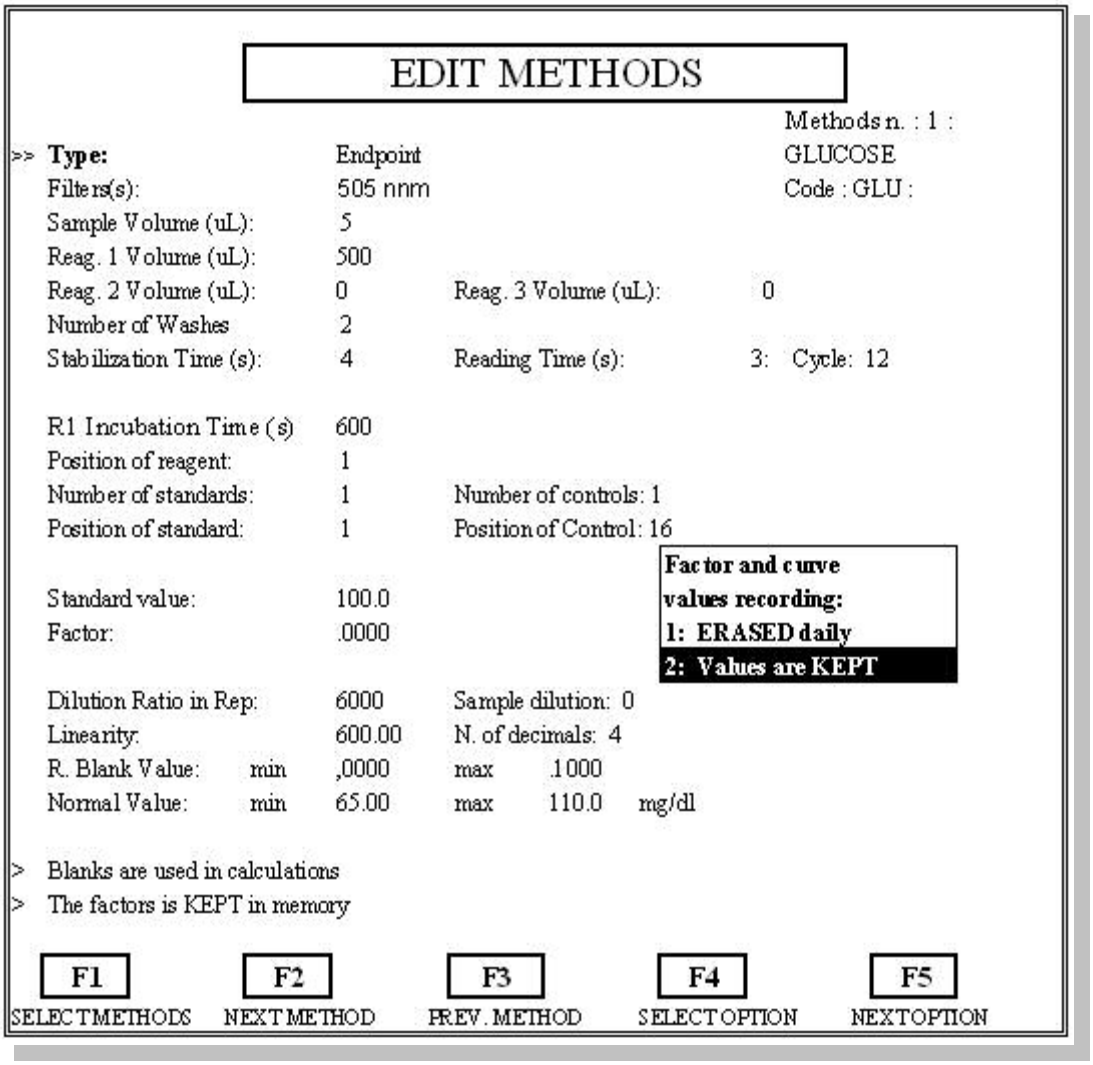

EDIT METHODS
Methods n. : 1 :
>> Type: Endpoint
GLUCOSE
Filters(s): 505 nnm
Code : GLU :
Sample Volume (uL): 5
Reag. 1 Volume (uL): 500
Reag. 2 Volume (uL): 0
Reag. 3 Volume (uL): 0
Number of Washes 2
Stabilization Time (s): 4
Reading Time (s): 3: Cycle: 12
R1 Incubation Time (s) 600
Position of reagent: 1
Number of standards: 1
Number of controls: 1
Position of standard: 1
Position of Control: 16
Factor and curve values recording:
1: ERASED daily
2: Values are KEPT
Standard value: 100.0
Factor: .0000
Dilution Ratio in Rep: 6000
Sample dilution: 0
Linearity: 600.00
N. of decimals: 4
R. Blank Value: min ,0000 max .1000
Normal Value: min 65.00 max 110.0 mg/dl
> Blanks are used in calculations
> The factors is KEPT in memory
F1 SELECT METHODS
F2 NEXT METHOD
F3 PREV. METHOD
F4 SELECT OPTION
F5 NEXT OPTION

fig. 7.3.8

Choosing option **1**, the factor is not stored. When a standard is analyzed, the calculated factor is noted in the parameter 16 (factor) and is used for the successive sample, but it is discharged after the instrument shut down.

Choosing option **1** the factors are automatically stored. When a standard is analyzed, the calculated factor is noted in the parameter 16 (factor) and can be used for the future analysis.

7.4 Patients Handling

Pressing the **F1** button in the *Main Menu* (fig. 7.2.1), the following screen will appear (fig. 7.4.1):

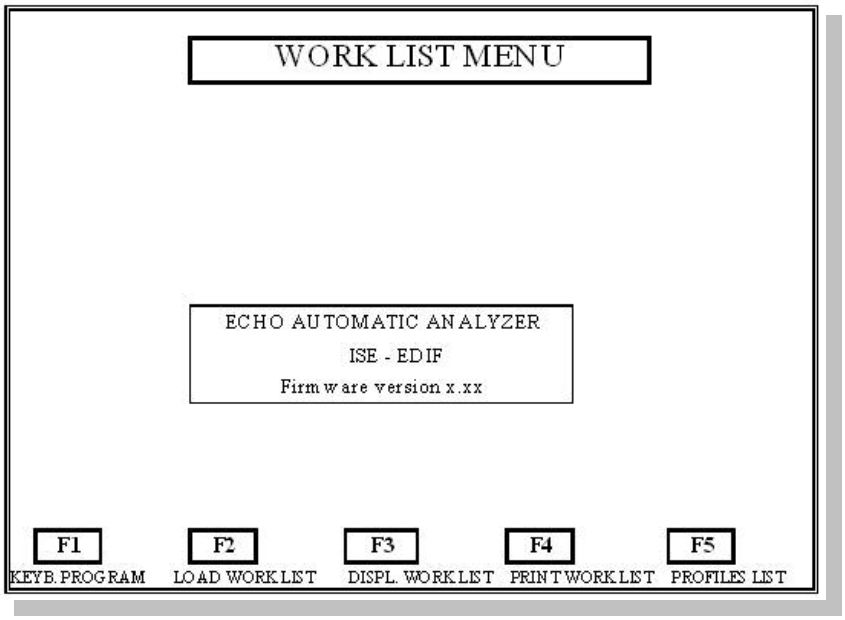


fig. 7.4.1

The available options are the following:

- ***Keybord Program*** (by pressing **F1**): allows to program the patient work list by the keyboard.
- ***Load Work List*** (by pressing **F2**): with is option is possible to load a work list from an external PC, using the serial port RS232.
- ***Display Work List*** (by pressing **F3**): displays the work list on the monitor.
- ***Print Work List*** (by pressing **F4**): allows to have a printout of the work list.
- ***Profiles List*** (by pressing **F5**): to display on the monitor the profiles list.

7.4.1 Edit Work List

Pressing the **F1** button, the software show three options (fig. 7.4.2):

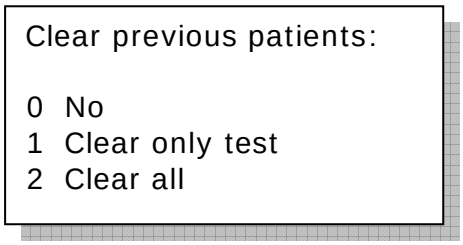


fig. 7.4.2

Press **0** button to not delete the existing database, **1** button to clear the tests but not the patients in the database and **2** button to clear all database.

After a choice will be displayed the following window (fig. 7.4.3):

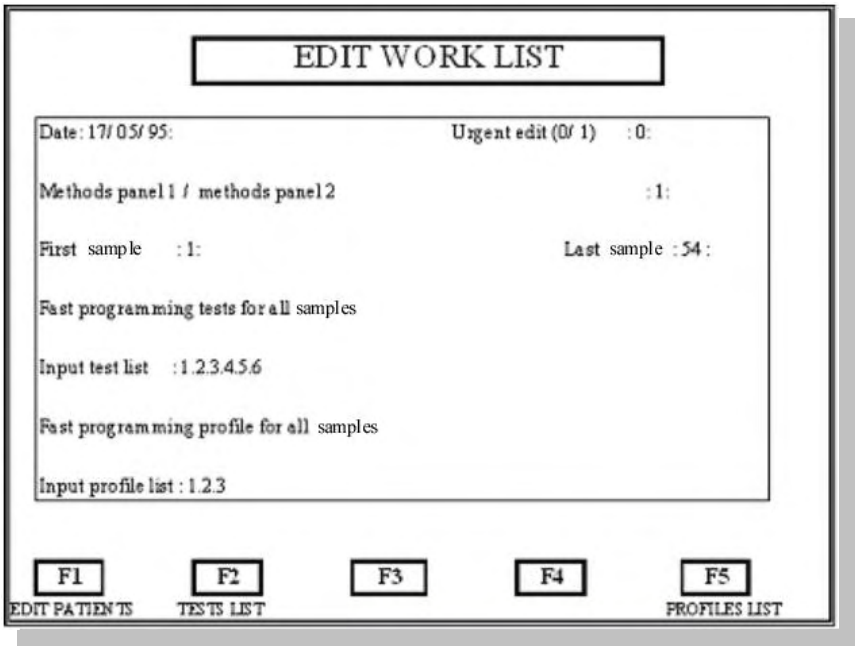


fig. 7.4.3

In this screen there are some information about the programmed work list, and in particular:

- *Date*
- *Urgent Edit*

  - **0**: corresponds to a normal edition; all the patients will be treated in the same way.
  - **1**: first will be treated the urgencies, the patients codifies as Urgent.

- *Methods Panel*: allows the selection of one of the two groups, each one with 32 methods.
- *Firs Patient*: up to 63 samples, the first patient number correspond to the position number on the sample plate.
- *Last Patient*: up to 63 samples, the last patient number correspond to the position number on the sample plate.
- *Input test list*: this numbers, separated by a dot, identify the tests that will be executed for all the patients (for fast programming only).
- *Profile test list*: this numbers, separated by a dot, identify the profiles that will be executed for all the patients (for fast programming only).

From this screen, pressing the **F2** and **F5** buttons, is possible to display the tests list and the profiles list.

Pressing the **F1** button the following screen will be displayed (fig. 7.4.4):

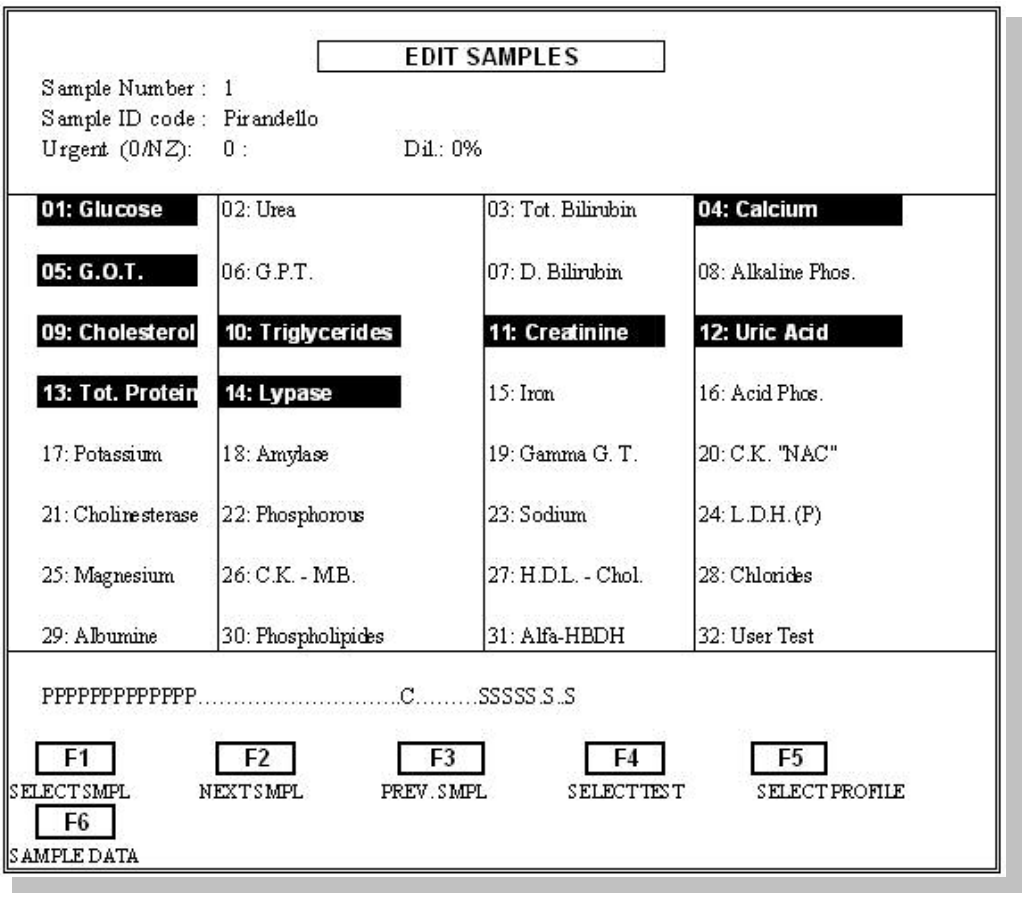


fig. 7.4.4

This screen allows to associate to a specific patient, the test or the profile that we want execute. On the upper part of the screen there are the patient data, on the lower part there are the tests.

To recall an existent patient, press **F1** button (*Select Patient*) and type the correspondent number. An other way is by pressing **F2** button (to go to the *Next Patient*) or **F3** button (to go to the *Previous Patient*).

A patient is identified by the following data:

- Sample ID code: an ID of 13 alphanumeric characters.
- Urgent (0 / NZ): 0 correspond to not urgent; 1 corresponds to urgent.
- Dil 0%: corresponds to the pre-dilution percentage.

To create or modify the data of a patient, select it and press the **F6** button; the following screen will appear (fig. 7.4.5):

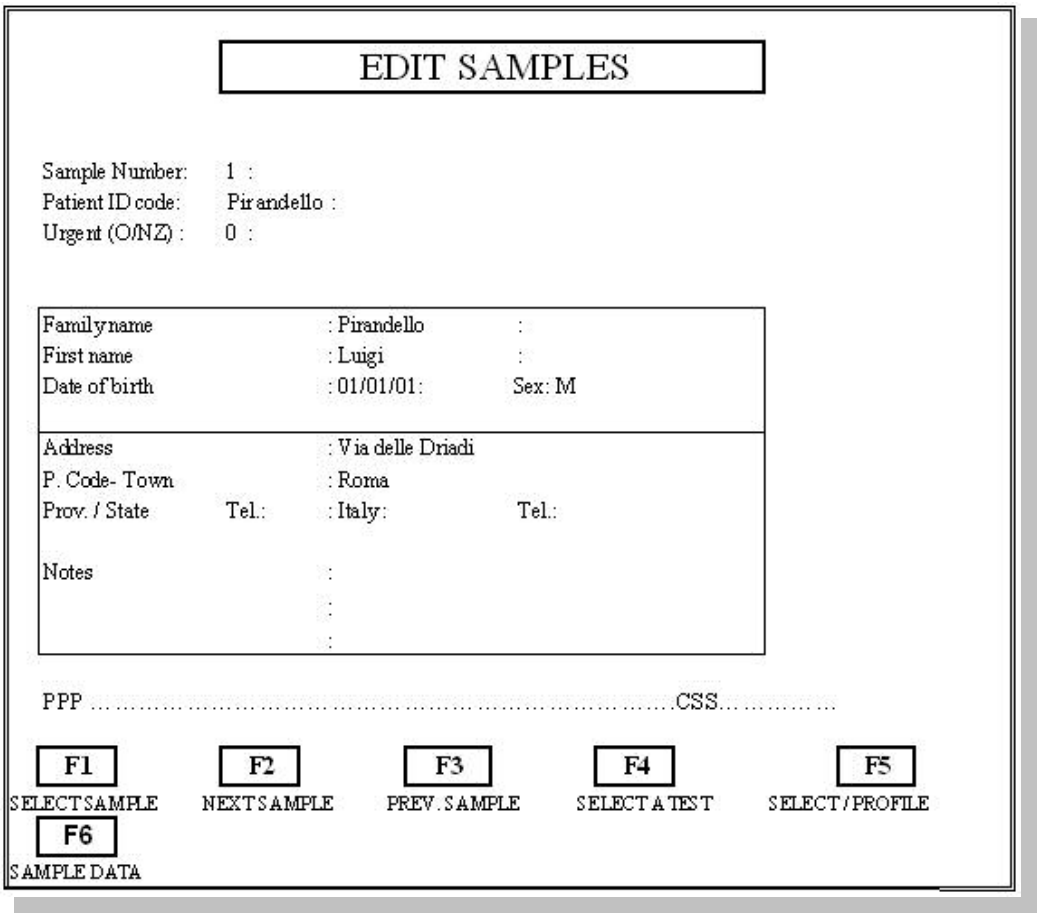


fig. 7.4.5

From here you can modify all the data that describe a patient.

Once you have selected the patient, you have to set the tests for that patient (refer to fig. 7.7.3). Use the cursor buttons to move though the columns, and in particular:

↑	Move up
↓	Move down
←	Move left
Enter	Move right

Select a test placing on it and pressing the **F4** button.

Another way to select a test is typing its numbers (from **1** to **32**) on the keyboard; to cancel the selection type again the test number.

The Del button allows to delete all the selected tests; the **Esc** or the **Page Up** buttons allow to return to the previous menu.

With the F5 button is possible to set a profile for the selected patients.

On the lower part of the screen will appear the work list program bar (see fig. 7.4.3), with 63 positions. The symbols on it have the following meanings:

- **P** = 1 one patient for a test's list
- **R** = 1 patient for a test's list and the previously memorized results.
- **C** = depending on the selected test, a control can be executed in this position.
- **S** = depending on the selected test, a standard can be executed in this position.
- **.** (dot) Indicates a free position.

7.4.2. Load Work List

Pressing the **F2** button in fig. 7.4.1, the software allows to load a work list from an external PC, through the serial port RS232.

NOTE: This option is valid only if an external PC is connected.

If the existing work list of the ECHO is not empty, the ECHO will ask if you want to erase the previous patients. Will be showed three options, type:

- **0** to stop the working list loading and to save the previous work list.
- **1** to load only the tests work list.
- **2** to load the patients and the work list of the test.

At the end of a correct loading the following screen will appear (fig. 7.7.6), to confirm that the operation is successfully completed:

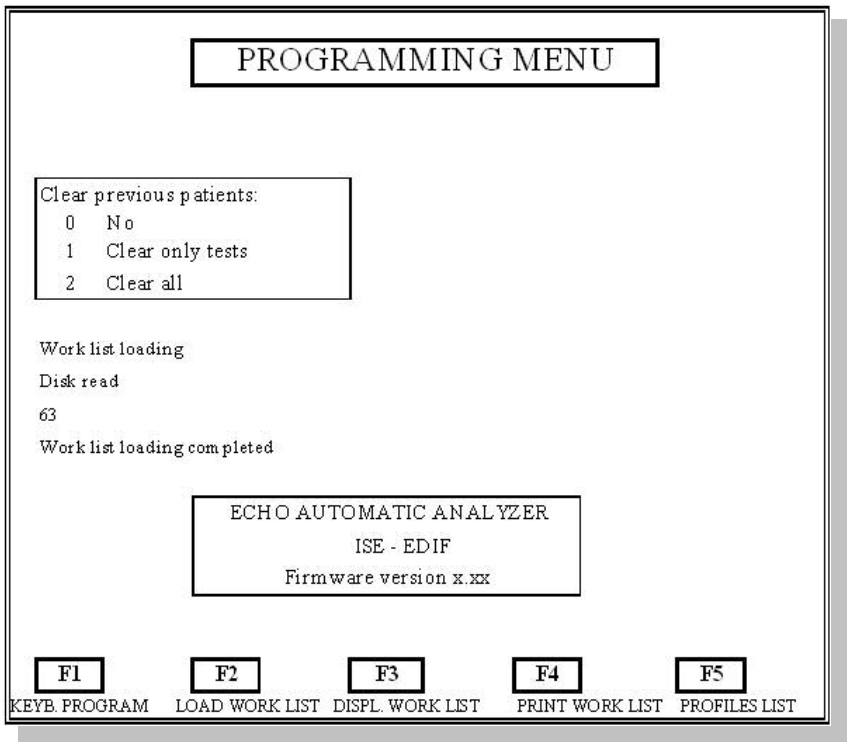


fig. 7.4.6

7.4.3 Display Work List

Pressing the **F3** button in fig. 7.4.1, the software allows to display the work list (see fig. 7.4.7):

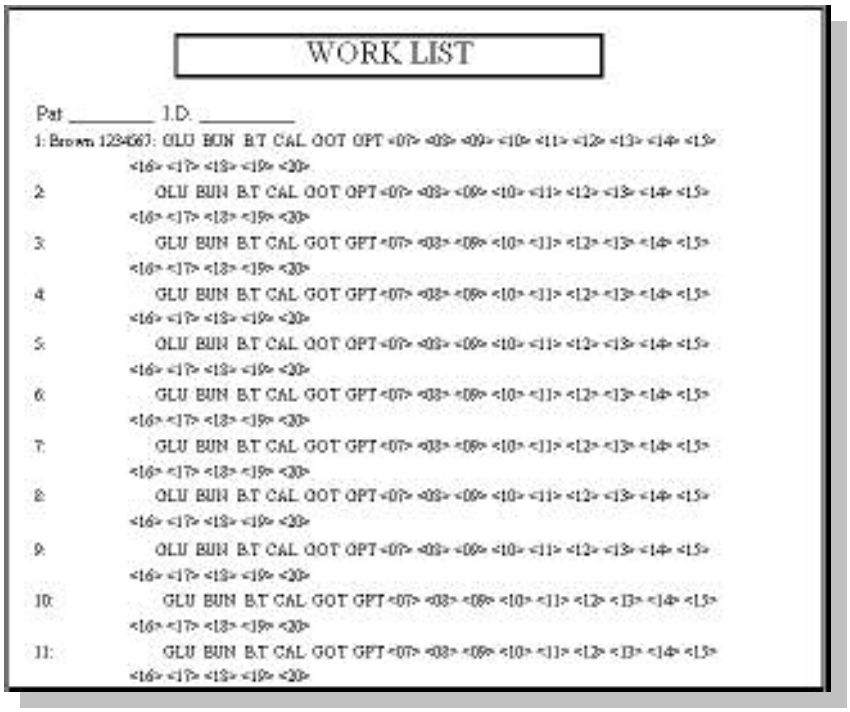


fig. 7.4.7

In the Pat column is showed the patient number, in the ID column there is the ID code of patient, followed by the list of the selected tests (number 1 to 32).

For the urgent patients the work list is visualized in bold. If the work list is longer than what appears on the screen, press a key to continue and press **ESC** to terminate.

NOTE: The tests are visualized per code or per number.

7.4.4 Print Work List

Pressing the **F4** button in fig. 7.4.1, the software allows to print the work list (see fig. 7.4.8):

Press the **F1** (fig. 7.4.8) button to print all the patients list, or press the **F2** (fig. 7.4.8) button to print only the urgent patients list.

7.4.5 Print Profile List

Pressing the **F5** button in fig. 7.4.1, the software allows to print the profiles list (see fig. 7.4.9):

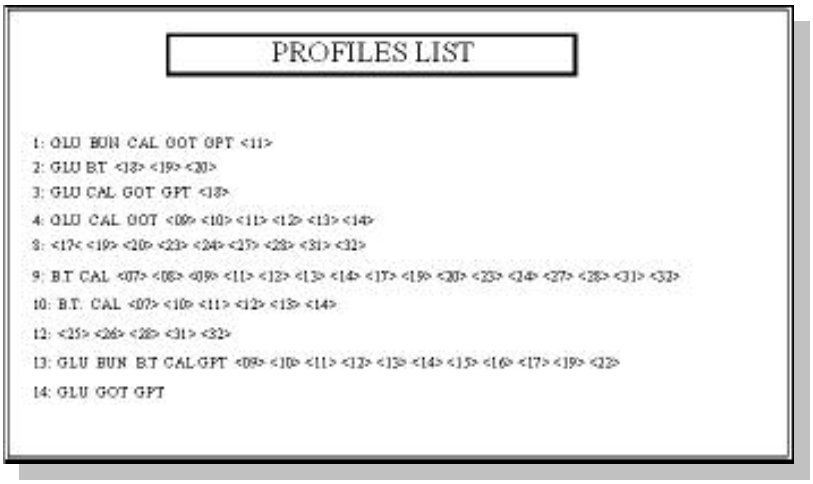


fig. 7.4.9

7.5 Operative Procedure

To have access to the Execution menu, press F2 button in the main menu screen (fig. 7.2.1); the following screen will appear on the monitor (fig. 7.5.1):

Note: it is possible to enter into the Execution Menu only in case there is already a Work list in memory.

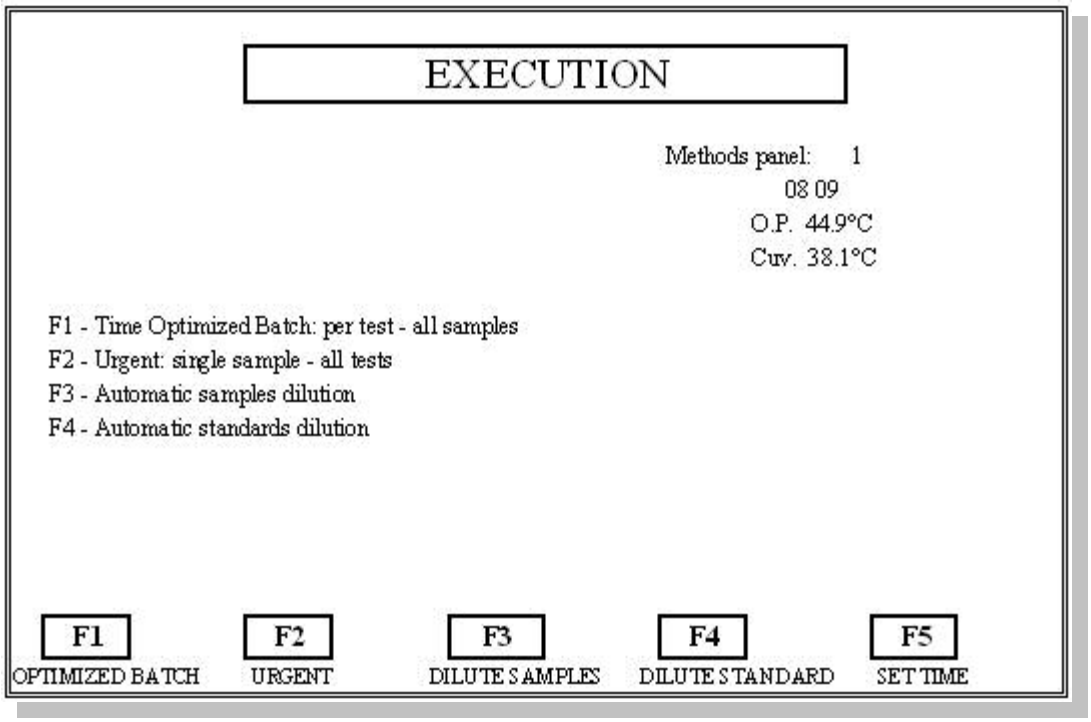


fig. 7.5.1

Batch mode: ECHO processes all the patients optimizing the times.

Urgent mode: ECHO analyses the sample one by one.

Automatic sample dilution: ECHO dilutes the patients for which the pre-dilution has been requested on the Work List patient.

Automatic standard dilution: ECHO dilutes the concentrated standard to create the necessary standards to produce the calibration curve.

For the **Optimized Batch** mode (**F1** button), the ECHO work according the following principles:

- Every cycle is composed of a complete wheel (96 wells).
- For every cycle is possible to insert up to 96 wells, including the first well for the blank reagent of each method, a well for each standard, a well for each control and a well for each test.

- For each test you can program up to 27 reagents; the tests with 2 reagents will take 2 places.
- Each method is executed completely in one cycle (the maximum per method is of 64 sample / test).
- The cycle is programmed for methods that don't use more than 96 wells. The methods over this limit will be executed in the successive cycle.
- At the end of execution, the ECHO will sign it with 3 bips and will come back to the execution menu to ask for the next cycle, until the execution of the entire programmed test.
- During the cycle, the end point methods, including the bi-chromatic ones, are distributed for first and will be measured at the end of the incubation time.
  During this interval, the Fixed Time methods, *kinetics* and *differentials* are executed. The ECHO will begin the sampling of the tests of one method, waiting the incubation time. When the incubation is terminated, the instrument reads the incubated sample and does a new sample alternatively.
  If the cycle is composed only by *End Point* methods, the same operational mode is used to increase the execution as much as possible. When a method has done all the samplings, the memorized number of washings will be done.
- At the beginning of each cycle, an auto zero procedure is executed.
- A washing procedure is executed at the beginning and at the end of each cycle.

For the **Urgent** mode (**F2** button), the ECHO work according the following principles:

- Only the patients signed as *Urgent* will be taken in consideration. The ECHO will execute one patient for time, for all the methods, with a maximum of 27 reagents.
- At the end of a patient working, the instrument will sing with 3 bips; the operator can verify the reagents and the sampling and can start a new test procedure.
- The principles are the same as the ones described in the Batch mode.
- For the successive patients the initial washings and the auto zero procedure are not effected.
- The blank reagent is executed only for the first patient on whom the method was programmed.

7.5.1 Batch

To run the *Batch mode*, press **F1** button in fig. 7.5.1. Next screen will be showed (fig. 7.5.2):

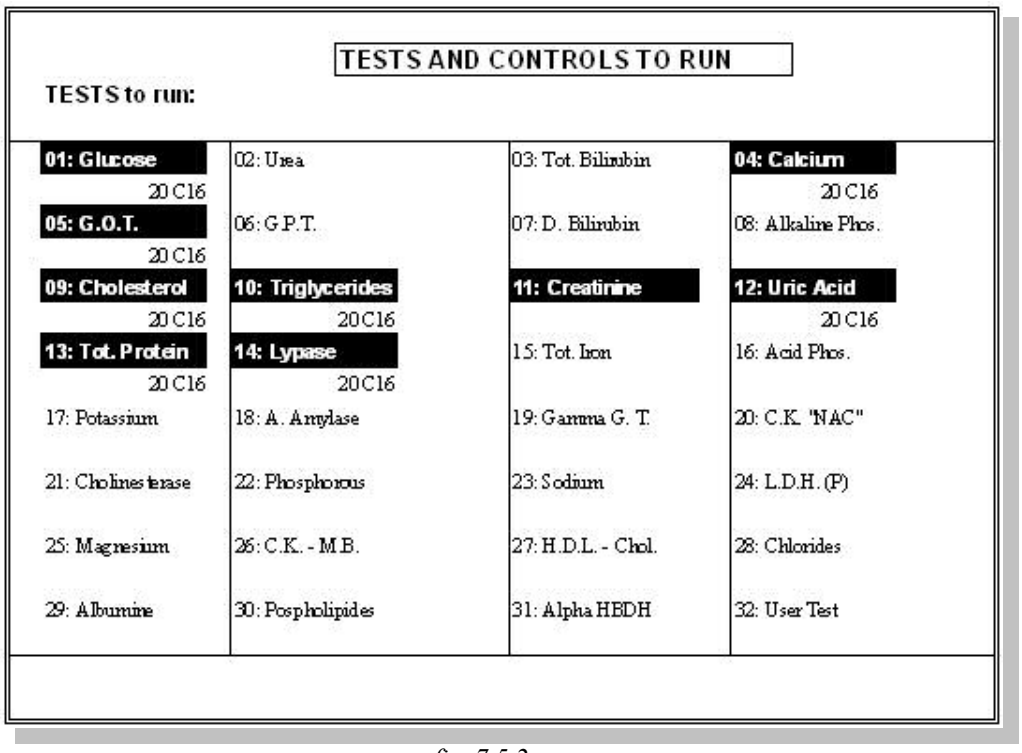


fig. 7.5.2

There are three steps to execute the assays: *Test Selection*, *Controls Selection* and *Standards Selection*. Those steps are detailed in the following paragraphs.

7.5.1.1 Tests and Control Selection

In this section the operator must confirm the controls and select the tests. To confirm all the selected tests without the controls, press the **F1** button (*Continue*).

To choose the tests press the **F2** button; to choose the controls press **F3** button; move the cursor through the columns, with the following buttons:

↑	Move up
↓	Move down
←	Move left
Enter	Move right

Select or deselect the test/control with the **F4** button. To switch all the controls on, press the **F5** button.

In the line with the method, the number of the tests to effect and the position of the control is indicated (C1 to C9), if a control has been inserted in the parameters.

After this operation press the **F1** button to go to the *Standardization procedure*.

7.5.1.2 Standardisation Procedure

In this section, the operator must select the standards to use. The methods are classified as follows:

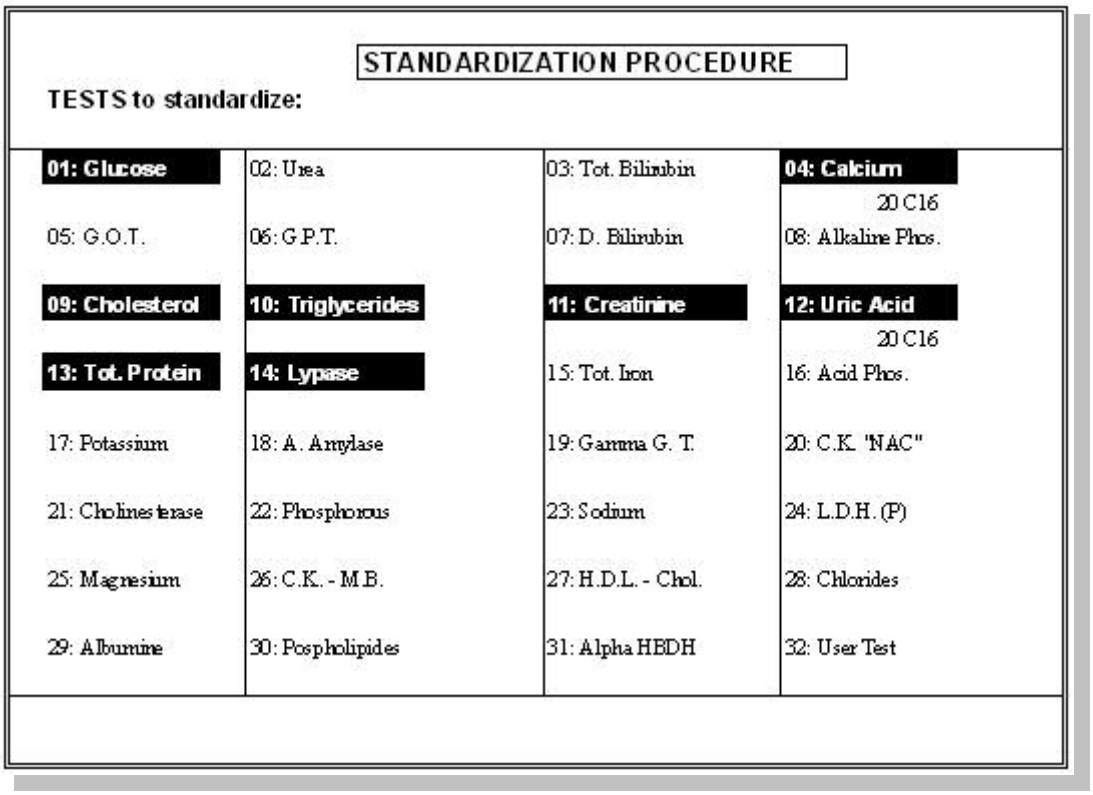


fig. 7.5.3

- The standard must be executed.
- The standard can be executed as an option.
- The standard is not necessary.
- The standard must be executed, but it can not be done (error).

Entering into the standardisation procedure, the standards that should be executed are already signed in bold. The operator can not cancel the selection, but can only select the standards to execute as optional.

The standard must be executed when:

- The method has a defined standard, the value of the standard is different from zero, the factor is zero.
- The method is defined as multistandard and the values of the O.D. curve are zero.

The standard can be executed as an option:

- The method has a defined standard, the value of the standard and the factor are different from zero.
- The method is defined as multistandard and the values of the curve are different from zero.

The standard is not necessary:

- The method does not require a defined standard and the factor is different from zero.

The standard must be executed, but it can not be done (error)

- The method has no defined standard, the factor is zero. The test can not be executed.
- The method has a standard with a defined value, the factor is zero and the value of the standard is zero. The following message will appear on the line 21:
  "ERROR" Method .xx. standard value null.
  The test can not be executed.
- The method is defined as multistandard and one or more values of the "n" standard is / are zero.
  The following message will appear on the line 21:
  "ERROR" Method .xx. N std. Xx, Curve n.x
  The test can not be executed.

If you select a standard for a method which does not require it, the ECHO will inform you with a beep signal.

In fig. 7.5.3. you can use the following buttons:

F2: Visualizes the programmed tests per reference.

F3: Visualizes the factors.

Under every method name is showed:

For the methods without standard:	Factor ? 0 Ex. F 1746
For the methods with one standard:	The standard and factor position are? 0 Ex. S1F1000
For the methods multistandard:	First standard position and number of standards. Ex. S1x8 The number of the curve. Ex. Curv. 13

F4: Selection and selection cancellation one by one.

F5: Selection of all the standards in option: ON

DEL/CTRL – FEED: Selection of all the standard in option: OFF.

To confirm all the parameters, press **F1**. The programming of the work execution can take up to 3 seconds (the opening of a window). After this operation a working cycle table will appear on the screen (fig. 7.5.4).

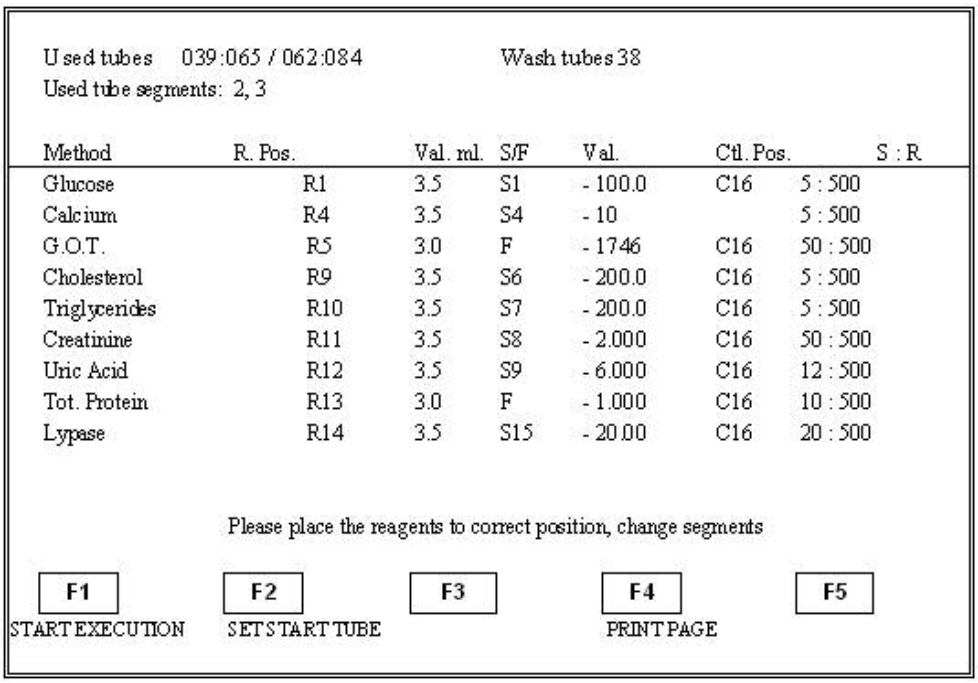

Used tubes 039:065 / 062:084
Wash tubes 38
Used tube segments: 2, 3
Method R. Pos. Val. ml. S/F Val. Ctl. Pos. S : R
Glucose R1 3.5 S1 - 100.0 C16 5 : 500
Calcium R4 3.5 S4 - 10 5 : 500
G.O.T. R5 3.0 F - 1746 C16 50 : 500
Cholesterol R9 3.5 S6 - 200.0 C16 5 : 500
Triglycerides R10 3.5 S7 - 200.0 C16 5 : 500
Creatinine R11 3.5 S8 - 2.000 C16 50 : 500
Uric Acid R12 3.5 S9 - 6.000 C16 12 : 500
Tot. Protein R13 3.0 F - 1.000 C16 10 : 500
Lypase R14 3.5 S15 - 20.00 C16 20 : 500
Please place the reagents to correct position, change segments
F1
START EXECUTION
F2
SET START TUBE
F3
F4
PRINT PAGE
F5

fig. 7.5.4

In the first line of the screen is showed the number of the tubes to use; in the second line there is the number of the rack to use, then in the third line there is the number of the test to execute.

In the seven columns are detailed the method name, the reagent position (R. Pos), the reagent volume + 2 ml (Val. ml), the execution with factor (F) or mono/multi standards (S), with the standard/s position, the standard or factor value (Val.), the position of the control (Ctl. Pos.), the relation between standard and reagent volume (S:R).

The operator should control if everything is placed in the right order, with the correct volumes, and if the reagent segments (rack) are correct. The operator can change the initial bottle with the following procedure: press the **F2** button and digit number **1**, then **Enter**. The working cycle will start automatically from the segment **1** (the first well of the segment is always reserved for the washings).

After all the controls have been carried out, press **F1** button to start the execution.

7.5.1.3 Execution

When the execution starts, on the screen will be showed a series of tables that allow to monitor the instrument operation.

The first table is the '*Initial Washing'* one; then will be showed the '*Auto Zero Procedure*' table, a control is executed on the filters used for the programmed methods.

Furthermore, other tables will indicate, by analysis (in bold), which operation is in execution, in particular:

- Sampling, or control or test
- Standard incubation or control or test
- Standard reading or curve or test
- Washings

The following image (fig. 7.5.5) shows an example table:

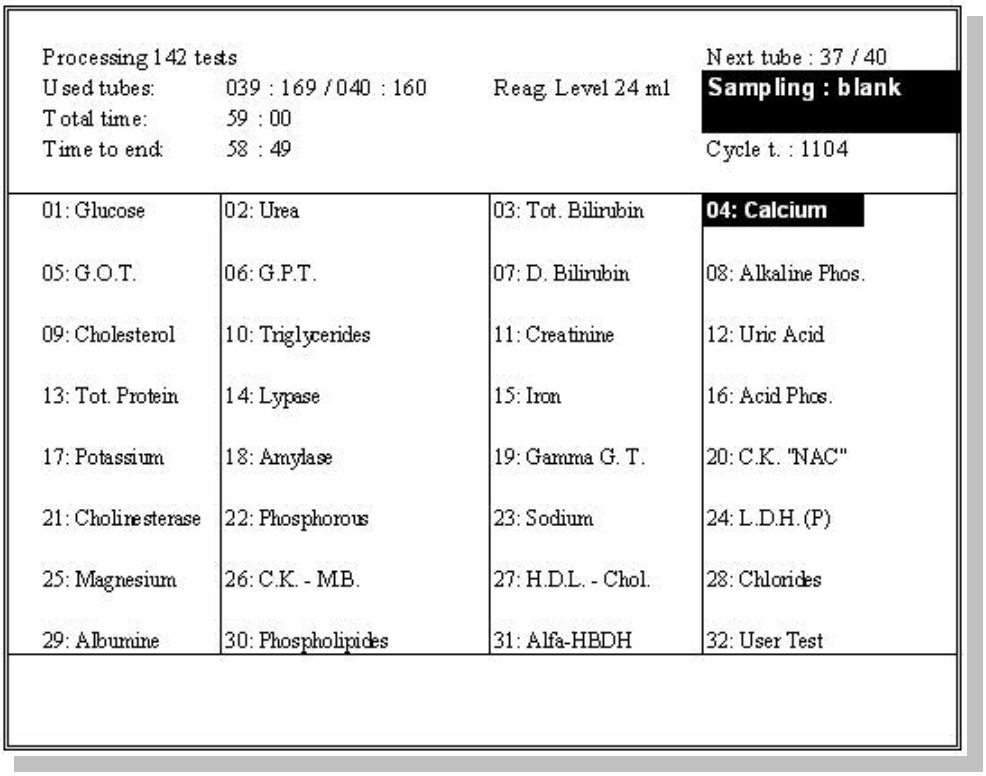


fig. 7.5.5

In this screen are detailed the following information:

Execution: **N**umber of tests to execute.

Wells used: Number of wells used for the cycle execution. The first one is the well used for the washings:

Total time: Time to execute the cycle (min and sec) + time to programming the work execution (in sec).

Final time: Remaining time to the end of the work cycle (min and sec).

Well: The last well used for the sampling.

Sample: Standard sample.

Cycle t.: Time to effect a simple cycle in 100 of sec.

7.5.1.4 Automatic sample dilution

To run the automatic sample dilution, in case there is at least one patient with the pre-dilution activated in the work list, press the Key F2 – Execution from the Main Menun and then press F3- Automatic sample dilution.

For ex. In case the patient n. 1 Daniele has in the work list activated the dilution in percentage, follow the below procedure:

Put an empty serum cup in the position n. 32 of the sample plate (the available positions for the dilutions are starting from the position 32 of the sample plate).

Put a reagent bottle in the position 27 with distilled water or physiological solution and press a key.

ECHO will proceed with the dilution.

7.5.1.5 Automatic standard dilution

From the Main Menu press F2 – Execution and F4 – Automatic standard dilution, in case you want to read for the first time a curve or you want to re-read it to reconfirm the calibration factors.

For ex. In case of a calibration curve with 5 standards put in standard position 5 on the sample plate a serum cups full of concentrated standard. Put in reagent position 27 a reagent bottle with distilled water and press a key.

Note: The above two procedures are suggested on the video.

7.6 Results Handling

At the end of the normal cycle execution, the ECHO will inform you by 3 signals and if there are other memorised tests to execute it will return to the Execution Menu, on the contrary will be showed the *Main* menu (fig. 7.2.1).

To read the tests results press the **F3** button in the Main menu; the following screen will appear (fig. 7.6.1):

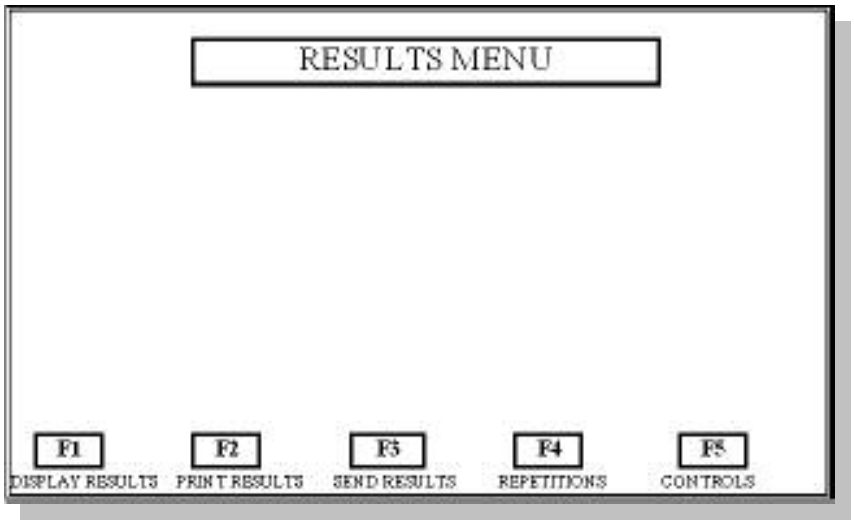


fig. 7.6.1

The five buttons showed on the bottom of the screen, have the following functions:

F1
DISPLAY RESULTS

Press this button to visualize the results per patient or per test.

F2
PRINT RESULTS

To print the results by group of patients.

F3
SEND RESULTS

Allows to load the results (and the working list) on a PC.

F4
REPETITIONS

To organize the repetition by test or by patient.

F5
CONTROLS

This function allows visualizes, prints, or erases the memorized values of the tests and controls.

7.6.1 Display Results

Pressing the **F1** button in the *Results* menu (fig. 7.6.1), will be showed the *Result Report* menu (fig 7.6.2):

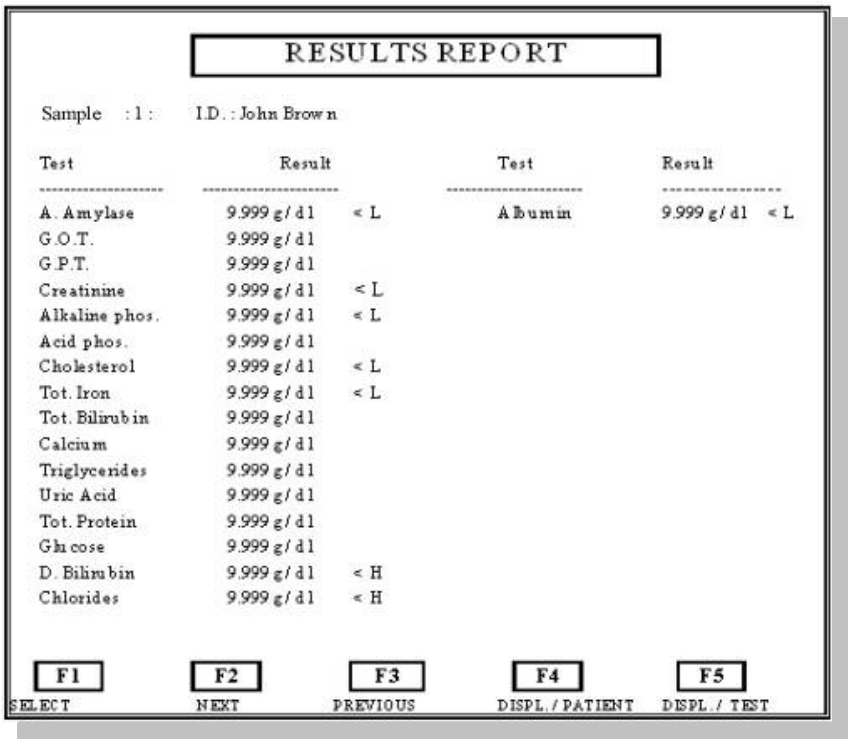

RESULTS REPORT
Sample : 1 : I.D. : John Brown
Test Result Test Result
A. Amylase 9.999 g/dl < L Albumin 9.999 g/dl < L
G.O.T. 9.999 g/dl
G.P.T. 9.999 g/dl
Creatinine 9.999 g/dl < L
Alkaline phos. 9.999 g/dl < L
Acid phos. 9.999 g/dl
Cholesterol 9.999 g/dl < L
Tot. Iron 9.999 g/dl < L
Tot. Bilirubin 9.999 g/dl
Calcium 9.999 g/dl
Triglycerides 9.999 g/dl
Uric Acid 9.999 g/dl
Tot. Protein 9.999 g/dl
Glucose 9.999 g/dl
D. Bilirubin 9.999 g/dl < H
Chlorides 9.999 g/dl < H
F1 SELECT
F2 NEXT
F3 PREVIOUS
F4 DISPL. / PATIENT
F5 DISPL. / TEST

fig. 7.6.2

The **F4** and **F5** buttons allows to choose the visualization mode, by patient (F4) or by test (F5).

The **F2** and **F3** buttons allows to display the next or previous patients/tests.

With the **F1** button is possible to choose a patient (or a test) simply typing the patient (test) number in the *Patient* (*Test*) field, on the top of the screen.

7.6.2 Print Results

Pressing the **F2** button in the *Results* menu (fig. 7.6.1), will be showed the *Print Patients Report* menu (fig 7.6.3):

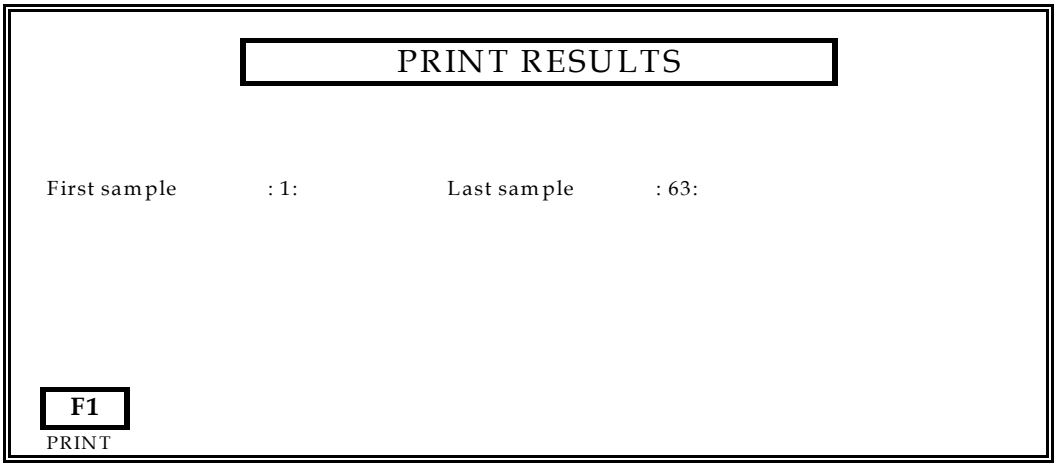


fig. 7.6.3

Now insert in the fields the *First* and the *Last* patient which should be printed.

Press the key F1 – Print.

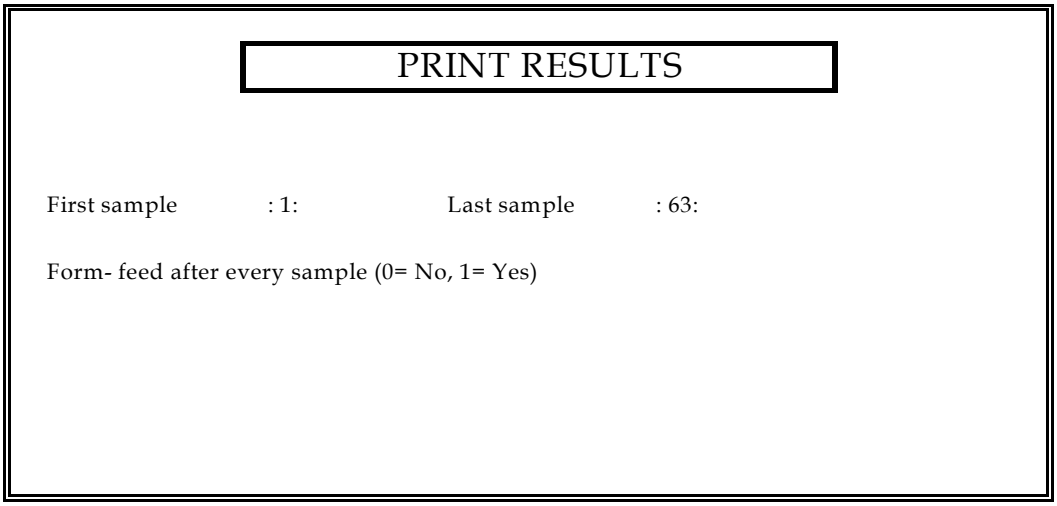


fig. 7.6.4

Choosing 0 the patients will be printed in sequence without heading, choosing 1 we will have a patient report complete of heading printed on the external printer.

NOTE: The patients which have no results will not be printed.

7.6.3 Repetitions

After the execution of a tests cycle, the operator can ask some repetitions to be done. There are 2 functions to use.

Pressing the **F4** button in the *Results* menu (fig. 7.6.1), will be showed the *following screen* (fig 7.6.5):

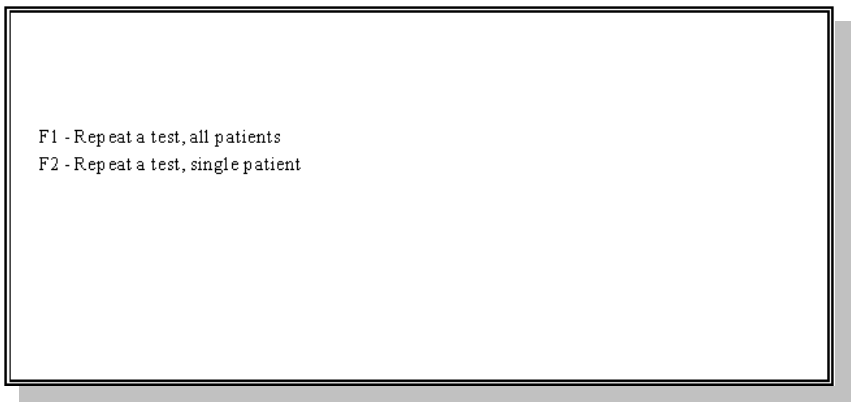


fig. 7.6.5

With this menu, the operator can carry out some repetitions after the execution of a tests cycle. Two functions are available; pressing the **F1** button will repeated one test for all the programmed patients. With the **F2** button will be repeated one test for only one patient, with the possibility of an auto-dilution.

7.6.3.1 Repetition of One Test for all patients

Pressing the **F1** button in fig. 7.6.5, will be showed the following screen (fig. 7.6.6):

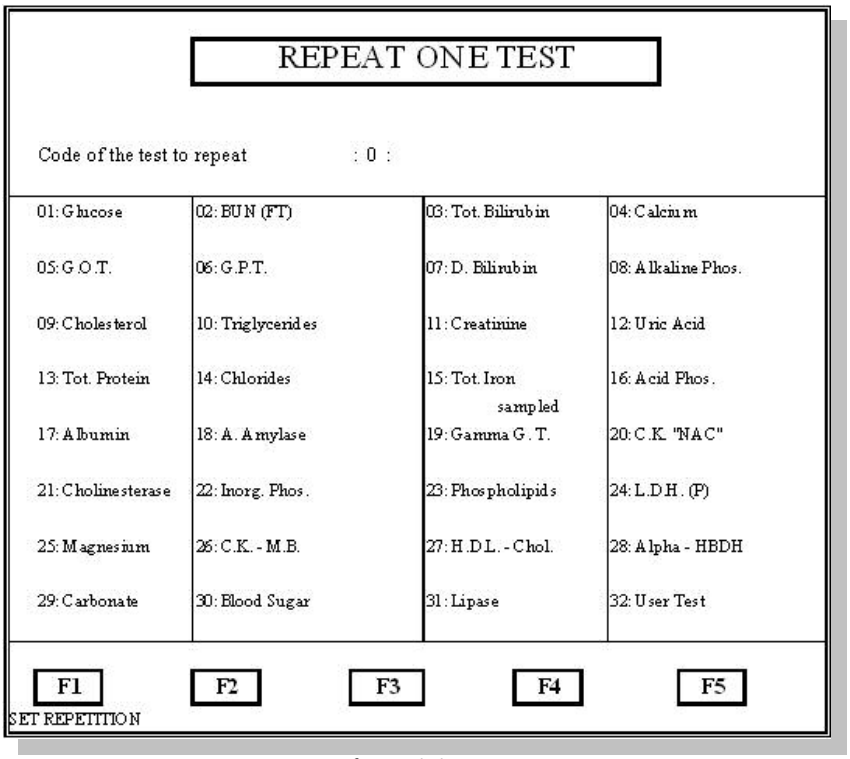


fig. 7.6.6

Now type the code of the test to repeat and press the **F1** button to activate the test repetition for all the programmed patients.

The activated tests are marked in bold. Repeat this operation for all the tests to repeat and then press **Pg Up/ BackMenu** button.

7.6.3.2 Repetition of One Patient

Pressing the **F2** button in fig. 7.6.5, will be showed the following screen (fig. 7.6.7):

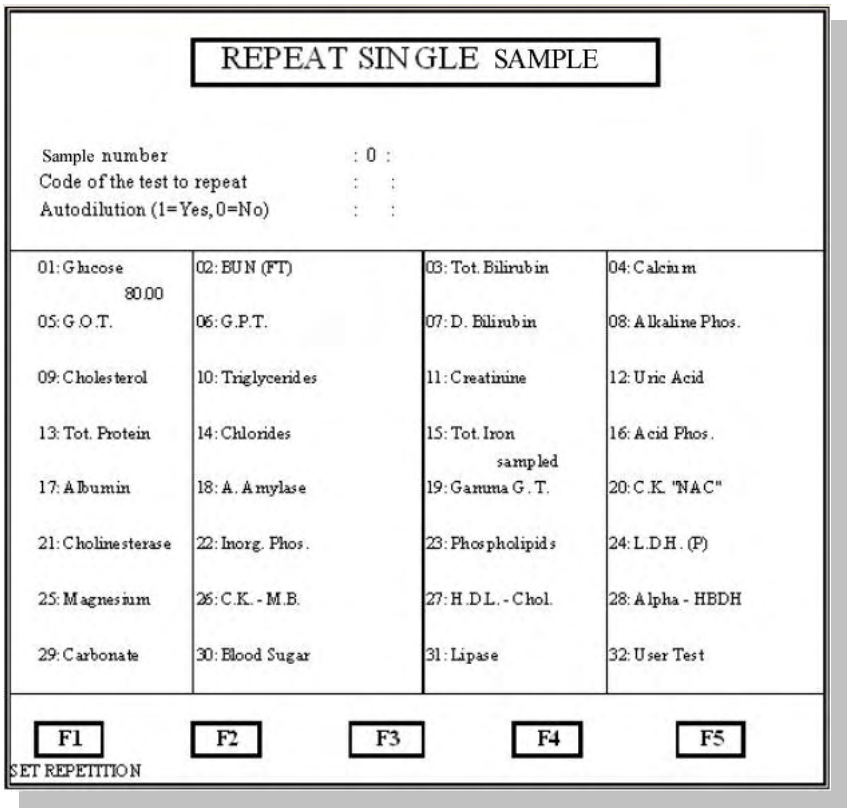


fig. 7.6.7

Type the number of the patient to repeat, the code of the test and the auto dilution parameter. Press **F1** to activate the test repetition.

If the patient doesn't have that test programmed, the ECHO will inform you with a beep.

If there are several tests activated for the patient these will be signed as urgent.

Program an auto dilution in case the sample is concentrated or if the results are not linear. In this case during the execution, the sample will be diluted as defined in the methodology (Chemicals – Method Edition).

The activated tests will appear in bold. Repeat the operation for all the tests to execute.

Press **Pg Up/ BackMenu** to exit or to change for another patient.

7.6.4 Controls

Pressing the **F5** button in the *Results* menu (fig. 7.6.1), will be showed the *following screen* (fig 7.6.8):

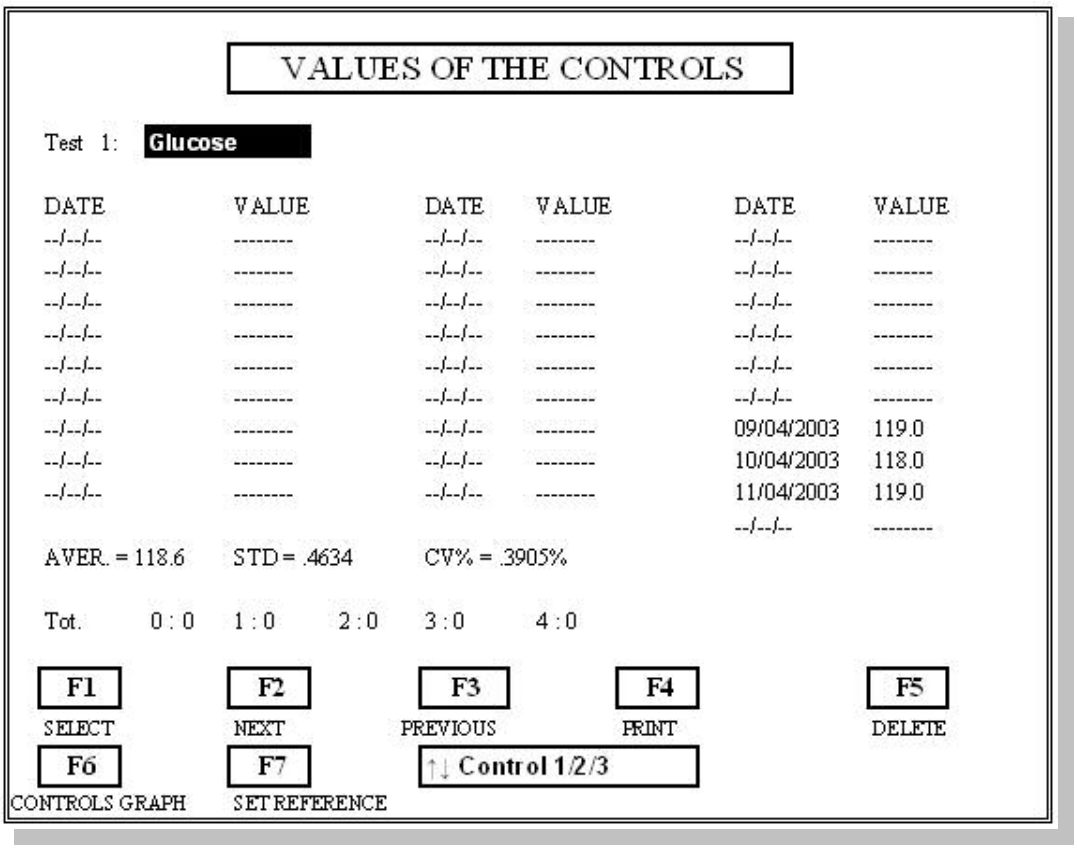


fig. 7.6.8

The ECHO memorizes up to 30 values of control of 32 + 32 tests.

When a new control is executed, the ECHO will re-write the new values on the old ones if the date is the same. If the date of the last control is different it will be added to the controls.

In the fields on the bottom of the screen are detailed:

AVER. ⇨ Average value of the memorized controls values.

STD. ⇨ $\frac{Average}{n-1}$ (n: number of controls).

CV% ⇨ Percentage of $\frac{STD}{AVER}$

To select the method, press:

F1: to select method typing its number

F2: allows the selection of the successive methods (1-32)

F3: allows the selection of the previous methods (1-32)

With the **F4** button is possible to print the controls and the selected methods; the **F5** button allows to erase the controls of the selected methods.

F6: visualizes the Levy-Jennings graphics

F7: to setup theoretical, the minimum and maximum value of the control sera

↑ ↓ **Control 1/2/3:** pressing the ↑ ↓ we can choose to visualize the quality control of the normal, abnormal low and abnormal high control sera.

7.7. Urgent Analysis

To introduce an urgent sample during a cycle, it is necessary to stop momentarily the cycle by pressing the **Esc/Stop** button. The following message will be showed (fig. 7.7.1).

fig. 7.7.1

The ECHO will inform you by a 10 seconds beep signal; during this gap the user can proceed as follows:

Esc / Stop: This button will block the instrument and the execution will be lost.

Enter: The execution cycle will continue.

1: The best choice – the instrument will finish the tests in course, and will be ready to take the urgencies.

NOTE: The urgency is inserted with the standard procedure Work list: in the *Patient Edit* menu press 0 button (do not erase the previous patients), then in the *Execution* menu press F2 button (*Urgent*).

At the end of the urgency cycle, the instrument will inform you with a beep, then it will return to the *Execution* menu; press 1 button (*Batch* mode) to restart the stopped cycle.

7.8. Dismantling

For the disposal of liquids, parts of the instrument and the instrument itself, the user must refer to the local regulation and to the law recommendations.

To dismantle liquids and parts, read carefully the following sections.

7.8.1 Reagents, Consumable and Toxic

Reagents, consumable and toxic must be dismantled according with regional laws. All waste materials must always be treated as potentially infected materials (see par. 1.4.3 'Information on Infectious Liquids and Parts').

7.8.2. Instrument and Components

The dismantling of the product should be carried out by applying the local regulations, referring to the local environment authority, taking into consideration that the instrument is manufactured with no noxious materials for the environment but, during the usage, it could be contaminated with infected materials (see par. 1.4.3 'Information on Infectious Liquids and Parts').

8. MAINTENANCE

8.1. User Maintenance Basics

This section will provide the user with general recommendations for the periodical maintenance.

WARNING

Failure to follow the maintenance procedure could compromise the performance of the system.

- Keep the ECHO work area clean and free of debris.
- Spills on working surfaces should be wiped and rinsed immediately with water.
- Continuous instrument inspection is critical for optimum equipment performance.
- All waste materials should be disposed of according to accepted safety guidelines and local regulations.
- In case of faulty or broken instrument parts, repair or replacement should be performed immediately by qualified technical support personnel.
- Read carefully the information on infectious liquids appended to this manual (see Section 1).

8.1.1. Competence

Any repairs, adjustments or replacements of parts, should be carried out by Technical Support Personnel only.

Daily, weekly and monthly routine maintenance procedures must be carried out by the user designated to operate it.

8.1.2. Cleaning

The plates and the working area should be cleaned, using a soft cloth.

WARNING

Before using any cleaning or decontamination method except those recommended by the Manufacturer, users should check with the Manufacturer that the proposed method will not damage the equipment.

8.1.3. Disinfections

This section covers the description of the indispensable information about instrument disinfection.

WARNING

Read the Safety Section 2 very carefully before coming out any maintenance.

For all the disinfection activities wear a protection overall with long sleeves ending with rubber bands, resistant rubber gloves and protection glasses.

Prepare two Sodium hypochloride solutions (commercial hypochloride): one at 1% and the other at 0.5%. Generally, commercial hypochloride has a concentration at 5,25%, if so, prepare the solutions as follows:

Solution A (approx. 1%): 200 ml of hypochloride and 800ml of deionised water

Solution B (approx. 0.5%): 100 ml of hypochloride and 1000ml of deionised water.

8.1.3.1. Instrument Disinfection Procedure

First, moisten those surfaces where you can see traces or incrustations of contaminated liquids with cotton wool soaked in solution A. Successively, remove the incrustations and moisten the above areas, again with the same solution. Those parts must remain moistened for at least 15 minutes, to obtain a good level of disinfection. When finished, remove the hypochloride with cotton wool in deionised water.

8.1.3.2. Metallic Needles

Carefully unscrew the two needles and soak them in a container with solution A for 15-20 minutes and then carefully rinse them with deionised water.

8.1.3.3. Waste Tube (External)

Discard the waste tube in the waste-container for contaminated materials. Replace it with a new one. Alternatively, if the tube is not deteriorated, you may leave it soaking for 20 minutes in solution A; afterwards rinse the tube well with tap water.

8.1.3.4. Waste Tank

Empty the waste container completely.

Fill the tank with solution A and leave it soaking for about 20 minutes and then carefully rinse it with deionised water.

8.2. User Maintenance Warnings

Work only with the instrument off and the power cable disconnected.

Serious damage to the vacuum pump can occur if there is too much fluid in the condensation trap.

8.3. User Daily Maintenance Procedure

Daily maintenance consists in the following steps.

- Thorough rinsing of the ECHO analyser's hydraulics will prevent the formation of salt crystal that can clog tubes and valves.
- Wipe up and disinfect any spills on the working area.
- Remove all reagents from the reagent plate. Wash the plate in case of spills. Disinfect if material is potentially contaminated.
- Remove all sample tubes from the sample plate. Wash the carousel with disinfectant in case of potentially contaminated spills.

Please, read carefully the following important recommendation:

- Inspect the instrument for leakage and spills. Should you find any, remove the liquid promptly. Refer to Section 1 on infectious liquid.

8.4. User Weekly Maintenance Procedure

In addition to regular daily maintenance, the following weekly decontamination procedure is recommended. The weekly decontamination may vary according to instrument use and is therefore user defined.

You have to carry out all the steps listed:

- Thorough rinsing of the ECHO analyser's hydraulics will prevent the formation of salt crystals that can clog tubes and valves. Empty the used tips tray, disinfect and wipe dry.
- Wipe up and disinfect any spills on the working area.
- Clean the exterior of the metallic needles (if in use) with 70% ethanol. Check that the metallic needles are firmly in place.
- Remove all disposable cups and reagent containers. Inspect the reagent plate tray for spills, leaked solutions or salt crystals. Rinse with distilled water and wipe dry. Disinfect if material is potentially contaminated.

9. TROUBLESHOOTING

9.1. Normal Operation Basics

9.2. Diagnostic System

9.3. Trouble Sources Classification Remarks

9.4. Correct Operations Messages

9.5. Error Messages List and User Required Actions

Generic error codes:

Problem	*Possible Causes / Actions*
No reagent and sample sampling and dispensing.	- Syringe module not connected. - Sapling tube broken. - Sampling tube not connected. - Pinch valve not functioning.
Washing solution is not dispensed.	- Empty bottle. - Defective valve. - Control the tubes connections.
The syringe has difficulties in filling and / or emptying.	- Verify the washing solution. - Verify the valve. - Control the piston (losses, blocks). - Execute a washing of the tubes. - Disconnect and clean the syringe.
Not repetitive analysis.	- The sampling probe is dirty. - Control the washing solution. - Change the needle cleaning filter. - Air bubble in the syringe. - The flow cell is dirty. - The reaction segments re –used (***mono use***). - Peristaltic pump tube consumed (***change periodically***).
Non constant aspiration in the flow cell.	- Check the aspiration tube. - Check the peristaltic pump tube. - Control the flow cell probe mechanism.
Air bubble in the flow cell.	- Tube broken or not correctly connected. - Loss in the flow cell (control the flow cell holder).
Auto zero error.	- Flow cell empty. - Bubbles in the flow cell.

Controls out of range.	- Losses in the connection tubes. - Dirty washing solution. - Halogen lamp expired. - Halogen lamp burned. - Peristaltic pump tube. - Compare the method with the control values. - Respect the correct working conditions and control the method. - Verify the water used for the reconstruction of the lyophilised reagents, serum controls. - Verify the reagent preparation in accordance with the instructions of the producer.
Aspiration arm going down without aspirating.	- Control the peristaltic pump tube and eventually substitute the same. - Controls that the tubes are not broken or clogged. - Control the pump assembly.
The instrument is not executing its initialisation.	- Shut down the instrument and turn it on after few seconds. - Call the technical assistance.
The internal printer is not functioning.	- Verify the thermal paper, its insert and the absence of blocks.

9.6. Competence

10. TECHNICAL SPECIFICATION

10.1. Instrument Technical Specification

ECHO's technical characteristics are listed in the sections below.

10.1.1. Sample Loading

- **Sample tubes on sample plate** : 64
- :
- :

10.1.2. Sera and Reagent Pipetting Station

- **Syringe Dilutors** : 1 dilutor with n.1x1ml precision syringes.
- **Syringe Resolution** : 3000 steps on max. stroke.
- **Carry-Over** Metal needle: < 10 ppm with 1ml wash volume

10.1.3. Incubating Station

- **Incubating area** : 1 room, 4 racks, 96 wells.

10.1.4. Photometric Reading

- **Reading range** : 0 ÷ 3.0 OD
- **Reading method:** : Single, double or double beam with over-range filter vertical reading
- **Reading filters** : 8 interference filters. Standard supply is 340, 405, 492, 505, 546, 578, 630, 700.

10.2. Adjustement and Settings

No settings are required from the instrument User.

All mechanical and electronic adjustments must be performed by technical personnel.

10.3. Electrical Requirements

- **Voltage** : 110V to 240V manual setting
- **Frequency** : 50-60 Hz

10.4. Operating Environmental Requirements

- **Temperature** : 15°C to 35°C
- **Humidity** : 20% to 80% RH not condensing
- **Altitude** : 0 to 2000 meters

10.5. Storage Environmental Requirements

- **Temperature** : 10°C to 35°C
- **Humidity** : 5% to 95% RH not condensing
- **Altitude** : 0 to 9000 meters

10.6. Emissions

No risks related to gas emission, implosion or explosion of parts is present.

10.7. Electromagnetic Compatibility

The instrument complies with the standard EN60326/A1.

10.8. Consumptions

- **Power** : 300 VA (typ)

11. SUPPLEMENTARY INFORMATION

11.1. Short User Instruction

11.2. Warranty Limitation

Edif Instruments S.r.l. warrants that all products of its manufacture (the "Product" or "Products") shall be free from defects in material and workmanship and is conform to Edif Instruments S.r.l. standard specifications for such equipment.

This warranty is subject to the equipment being used, operated, handled and maintained by the Buyer under normal conditions in accordance with good operating practices, and in compliance with any written instructions furnished to the Buyer by Edif Instruments S.r.l., and is void as to any equipment modified, altered or damaged by persons other than Edif Instruments S.r.l..

Failures which are necessitated by inadequate or incorrect maintenance of the instrument by the customer, including accident, abuse, misuse or neglect, fare, theft, water or any other cause other than instrument failure, will violate the warranty.

The above described warranty, valid for one year from the installation, is on ex works Rome – Italy basis and the consumable parts such as tubes, syringes, lamps, flow cells etc. are excluded from the warranty.

11.3. Spare Parts ans Consumables

ECHO PC ACCESSORY BOX

	EDIF CODE	OLD CODE	
1	EI0703CV1	P10 0000 0023	Halogen lamp (MATE-N-LOCK connector)
1	EI0801B	P10 0000 0008	Tubes kit
1	EI0802A	P10 0000 0010	Sampling and Aspiration Needles kit
1	EI0710A	P10 1000 0001	Reagent bottles 25 ml (27 pos.) pack (30 pcs)
1	EI0711A	P10 1000 0002	Reagent bottle caps 25 ml (27pos.) pack (30 pcs)
1	EI0714A	P10 0000 0003	Needle cleaning filters pack
1	EI0715A	P10 0000 0004	Reaction segments pack (100 pcs)
1	EI0716A	P10 0000 0005	Serum cups pack (1000 pcs)
1	EI0717A	P10 0000 0006	Thermal paper pack (3 pcs)
1	EI0702B	P10 0000 0012	Fuses kit (230V)
1	EI0721A	P10 0000 0017	Water charge bottle
1	EI0722A	P10 0000 0018	Waste bottle
1	EE0203A	S10 2100 0009	Null modem host cable
1	EI0702B	P10 0000 0012	Fuses kit 230V
1	EI1126A		Brief user manual
1	EI0732A		Documentation CD
1	EE0202B		Power cord

ECHO PC CONSUMABLES

EDIF CODE	OLD CODE	DESCRIPTION	PACK
EI0710A	P10 1000 0001	Reagent bottles 25 ml (27 pos.) pack	30
EI0711A	P10 1000 0002	Reagent bottle caps 25 ml (27pos.) pack	30
EI0712A	P10 0000 0001	Reagent bottles 40 ml (18 pos.) pack	20
EI0713A	P10 0000 0002	Reagent bottle caps 40 ml (18 pos.) pack	25
EI0714A	P10 0000 0003	Needle cleaning filters pack	25
EI0715A	P10 0000 0004	Reaction segments pack	100
EI0716A	P10 0000 0005	Serum cups pack	1000
EI0717A	P10 0000 0006	Thermal paper pack	3
	P10 0000 0007	Tubes kit (old over with vertical diluter)	1
EI0801B	P10 0000 0008	Tubes kit	1
EI0822A	P10 2000 0003	Flow cell (new model, 10 x 10 mm)	1
EI0802A	P10 0000 0010	Sampling and Aspiration needles kit	1
EI0703CV1	P10 0000 0023	Halogen calibrated lamp with support (MATE-N-LOCK connector)	1
EI0703C	P10 0000 0011	Halogen calibrated lamp with support (old MX396 connector)	
EI0701B	nd	Fuses kit (115V)	1
EI0702B	P10 0000 0012	Fuses kit (230V)	
EI0719A	P10 0000 0013	Diluter Syringe complete of plunger	1
EI0832A	P10 0000 0015	Flow cell quartz + O-ring kit (old flow cell)	2
EI0102A	P10 0000 0016	Heating reel	1
EI0721A	P10 0000 0017	Water charge bottle	1
EI0722A	P10 0000 0018	Waste bottle	1

ECHO PC SPARE PARTS

EDIF CODE	OLD CODE	DESCRIPTION	QTY ON BOARD
EI0201A	S1001000001	Optical limit switch	7
EI0202A	S1001000002	Cooling fan for power board	2
EI0244A	nd	Bottom cooling fan	1
EI0203A	S1001000003	Diluter solenoid valve	1
EI0204A	S1001000004	Peltier cell for optics	1
EI0205A	S1001000005	Heating etched foil resistance (outer plate)	1
EI0206A	S1001000006	Heating etched foil resistance (pre-heating reel)	1
EI0207A	S1001000007	Sampling and aspiration needle step motors	2
EI0208A	S1001000008	RP, IP, OP, FS. PM stepper motors	5
EI0210A	S1001000011	Flow cell temperature sensor	1
EI0211A	S1001000010	Outer (reaction) plate temperature sensor	1
EI0212A	S1001000009	Diluter stepper motor	1
EI0213A	S1001000012	Optical pre-amplifier assembly	1
EI0218A	S1001000017 (2)	Boards interconnection flat cable	2
EI0220A	S1001000019	Reagents plate rotating wiring kit	1
EI0222A	S1001000021	Optical signal cable	1
EI0223C	nd	Low-voltage wiring assembly (AMPMODU, MATE-N-LOCK)	1
EI0223B	S1001000022	Low-voltage wiring assembly (old MX396 connectors)	==
EI0224B	S1001000023	High - voltage wiring assembly	1
EI0226A	S1001000025	Stepper motors protection diodes modules	8
EI0301B2V1	nd	Power board (AMPMODU green connectors)	1
EI0301B2	S1001000026	Power board (MX396 old white connectors)	==
EI0302B1V1	S1001000027	CPU board	1
EI0302B1	nd	CPU board (old version with CRT controller)	==
EI0214A	S1001000013	Internal printer assembly	1
EI0307B	S1001000028	Power supply transformer assembly	1
EI0401A	S1001000031	Power supply for reagent cooling	1
EI0245B	S1021000013	Level sensor module	1
EI0109C	S10 2100 0012	Internal PC PC104 assembly	1

11.4. Ordering Information

Refer to your local distributor.

11.5. Technical Assistance

The Technical Assistance will be provided through your local distributor.

11.6. Forms

The form in the next page regards the Training Course satisfaction; you are kindly requested to fill this anonymous questionnaire and to return it to the following address:

EDIF INSTRUMENTS S.r.l.
Via Ardeatina, 132
00179 Rome - Italy

TRAINING COURSE EVALUATION FORM

ACTIVITIES EVALUATION

Importance			*Specific Performance*	*Satisfaction / Mark*				
1	2	3	**Instrument Overview**	10	8	6	4	2
1	2	3	**OS Software overview**	10	8	6	4	2
1	2	3	**Application Overview**	10	8	6	4	2
1	2	3	**Operate the instrument**	10	8	6	4	2
1	2	3	**Evaluate results**	10	8	6	4	2
1	2	3	**Maintenance**	10	8	6	4	2
1	2	3	**Troubleshooting**	10	8	6	4	2

Legend:

Importance Level:	1 - Very important	2 - Important	3 - Not so important
Satisfaction Level:	10 - Extremely satisfied	8 - Very Satisfied	6 - Satisfied
	4 - Unsatisfied	2 - Very unsatisfied	

Missing features to be implemented, other comments or suggestions:

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Edif Instruments s.r.l. – Via Ardeatina, 132 – 00179 Roma – ITALY
Tel.+39/065127161 – Fax +39/065127550
email edif@edif.it

The form in the next page regards the Customer's satisfaction; you are kindly requested to fill this anonymous questionnaire and to return it to the following address:

EDIF INSTRUMENTS S.r.l.
Via Ardeatina, 132
00179 Rome - Italy

CUSTOMER'S SATISFACTION QUESTIONNAIRE

GENERAL OPINION ON INSTRUMENT'S PERFORMANCES

Importance	*Specific Performance*	*Satisfaction / Mark*
[1] [2] [3]	Pipetting	[10] [8] [6] [4] [2]
[1] [2] [3]	Reading	[10] [8] [6] [4] [2]
[1] [2] [3]	Productivity/throughput	[10] [8] [6] [4] [2]
[1] [2] [3]	Tests Programming	[10] [8] [6] [4] [2]
[1] [2] [3]	Software /User interface	[10] [8] [6] [4] [2]

Legend:

Importance Level: 1 - Very important 2 - Important 3 - Not so important

Satisfaction Level: 10 - Extremely satisfied 8 - Very Satisfied 6 - Satisfied
4 - Unsatisfied 2 - Very unsatisfied

Missing features to be implemented, other comments or suggestions:

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12. GLOSSARY

12.1. List of Acronyms and Abbreviations

ASTM	American Society for Testing Material. Standard transmission format for host communications.
AU	Absorbance Units.

12.2. List of Terms

Peristaltic pump	Device required by ECHO to aspirate liquid from the working area to a self-contained reservoir.
Absorbance	It is related the colour intensity of a liquid. Light passing through a dark liquid is 'absorbed'.
Autodiagnosis	A self-investigation or analysis of the cause or nature of a condition, situation or problem.
Barcode	Information that has been encoded in a bar and space format.
Beam	A ray or shaft of light.
Blank	Result value equal to no reaction.
Blanking	Reference value of the light intensity used to measure the absorbance of the liquid in the wells.
Calculus Engine	A data-processing program.
Database	A set of stored data used for search and retrieval.
Default	Value or Document, which is standardised, specific.
Dilutor pump	This unit ensures precise and accurate delivery of samples or reagents by means of a syringe.
End Work	Option to safely shut down the laboratory analyser.
Fill syringes	This feature enables a pipettor/dilutor cycle the. The cycle will have the effect of purging any air bubble out of the hydraulic system.
Halogen lamp	Lamp used to generate the light required during the reading step.
HTML format	A standard format for internet pages.
Incubating station	Temperature controlled micro-chamber.
Interference filters	Calibrated filters used to distinguish the colorimetric reaction generated by enzymatic reaction.
Interpolator	Calculus program for regression analysis.
Login	Enables the access to the system via Password.
Logoff	Disables the access to the system.
Maintenance	Operation required weekly and monthly to clean and assure a good functioning of the analyser.
Metal needle	One of the two devices used for pipetting standards and samples.
Multiplication factor	Correction factors used when the optical density is out of limits and used in conjunction with an over-range filter.
Optical sensor	Electronic device on the receiving end of the photometer to convert light into electronic signal.
Over-range filter	Reading filter used when the reading exceeds the 2 OD limits and if it is foreseen in the reagent kit instructions. It must be used in conjunction with the Multiplication Factor.
Parallel dispensing	Simultaneous processing of plates up to first incubation.
Password	A sequence of characters required to access to computer system or to an application.
Photometric reading system	System consisting in a light source, discriminating filters and sensors. It is used to measure the colour intensity of the

	liquid in the wells at the end of the reaction.
Plate Blank	Blank value subtracted from all other values read on the microplate.
Procedure steps	Step by step instructions for a test run.
Processing Mode	It refers to the selection of parallel or serial dispensing.
Serial dispensing	A processing of the first plate up to the first incubation and then proceeding to the second plate.
Stepping motor	Special motors used for precise movement.
Waste tank	Tank where all the contaminated liquids are disposed.